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TAB C



Memorandum

Date:

08/02/2005

TO

Kristina M. Hatlelid, Project Manager

Directorate for Health Sciences

THROUGH:

Russell H. Roegner, Associate Executive Director R2

Directorate for Epidemiology

FROM

Robin L. Ingle, Health Statistician RM

Hazard Analysis Division

SUBJECT:

Petition Requesting Ban of Sulfuric Acid Drain Openers for Consumer Use,

Petition HP 04-02

A. Background

Drain openers on the market today consist of three types: alkaline, acid and enzyme. The retail drain opener market is dominated by alkaline products. Acid drain openers include products containing sulfuric acid and products containing hydrochloric acid. Injuries with sulfuric acid drain openers (SADOs) can result from several different scenarios. A victim may ingest the SADO, may inhale fumes produced by the SADO's reaction with another substance, or may come into dermal or ocular contact with the SADO.

Sulfuric acid reacts with water and other substances. A chemical reaction can occur when the acid contacts human flesh or when it is poured into a drain containing water or other substances. Under ideal circumstances, the latter situation results in an exothermic reaction that opens the drain. Under less than ideal circumstances, however, the heat produced can also result in spattering or eruption onto anyone in the vicinity. Dermal contact with sulfuric acid – which can also occur with spills – can cause serious burns. Drinking sulfuric acid can cause burns in the mouth, throat and stomach, and can be fatal (ATSDR, 1999). Ocular exposure to sulfuric acid can result in chemical burns to the eye (Brundage, 2005).

The U.S. Consumer Product Safety Commission (CPSC) has been petitioned to ban the use of SADOs for use by consumers or, alternatively, to require that SADOs for consumer use be "packaged in one-shot containers" and have a concentration of no more than 84 percent sulfuric acid (Fox, 2004; Martin, 2004; U.S. CPSC, 2004).

This memo gives the results of an analysis of data obtained since the last statistical analysis of data on drain openers by CPSC staff. It utilizes National Electronic Injury Surveillance System (NEISS) data from 1995 to 2003, paired with investigation documents from the In-Depth Investigation database (INDP). It also presents the results of an examination of fatal incidents in

CPSC's Death Certificate file (DTHS) and the Injury and Potential Injury Incident file (IPII) reported from 1996 to 2004. Recent poison control center data from the Toxic Exposure Surveillance System of the American Association of Poison Control Centers are also summarized.

A long history of statistical analyses of drain opener data exists at CPSC. This memo as a general rule will not restate the results or discussion from the previous memos, but will instead focus on the analysis of data obtained by the agency since the last briefing package on drain openers (Petition HP 95-03). The reader is directed to several analyses in older memoranda listed in the references section of this report. These are briefly noted here:

In 1981, CPSC staff produced several memoranda on injury and death data that were included in a briefing package on SADOs. Those analyses utilized data from NEISS for 1978 to 1980, and investigation data from 1976 to 1978, as well as several small data sets on file at CPSC (Drago, 1981; Jones, 1979; Jones, 1980; Jones, 1981).

In 1996, CPSC staff produced another analysis of injury and death data for inclusion in a briefing package on drain openers. That analysis utilized NEISS data from 1980 to 1994 and death certificate data from 1980 to 1995 (Kissinger, 1996).

B. Injuries

NEISS Data and Methodology

NEISS is a probability sample of about 100 U.S. hospitals with 24-hour emergency rooms and at least six beds. NEISS gathers data from its hospitals on emergency-room visits of people who have been injured using consumer products. The data are coded at the hospitals from the medical records and are transmitted electronically to CPSC. Each case in NEISS has an associated weight equal to the number of other cases from other hospitals that it represents. Different hospitals carry different weights, based on stratification by their annual number of emergency room visits (Kessler and Schroeder, 1999).

This analysis utilizes NEISS data categorized in product code 0929 (drain openers) from 1995 to 2003. Hazard Analysis staff searched NEISS for these incidents, retrieving 522 incidents from the database. CPSC's In-depth Investigation database (INDP) contains reports of investigations carried out by CPSC's field staff. Between 1995 and 2003, some drain cleaner incidents reported through NEISS were investigated. The investigators sought information on the type of drain cleaner involved, characteristics of the victim, the incident scenario, and other details. This information was used as an aid in generating subcategory estimates for the numbers of injuries treated in hospital emergency rooms.

Health Sciences staff and Hazard Analysis staff used the NEISS record and associated CPSC investigation to classify each case as involving a sulfuric acid, alkaline, hydrochloric acid drain opener, or a drain opener made of an acid of unknown type, or whose ingredients were unknown altogether. Some cases were identified as involving more than one of these or one of these plus

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another substance. These were classified as mixtures. After review of each NEISS case and its investigation, fourteen cases were deemed out of scope for this analysis, including cases that were intentional in nature or did not involve drain openers.

Hazard Analysis staff used SAS version 8 to compute estimates and the associated coefficients of variation for the number of injuries as well as the estimated numbers of injuries for victims with particular characteristics such as age and gender. Estimates for years prior to 1997 were adjusted to account for sampling changes in NEISS, and adjustments to the pre-1997 cases were also used in subcategory analysis.¹

Because NEISS is a probability sample, estimates calculated from NEISS have sampling variation. The coefficient of variation (C.V.), an expression of this, is the ratio of the standard error of the estimate (i.e. variability) to the estimate itself. This is generally expressed as a percent. A C.V. of 10 percent means the standard error of the estimate equals 0.1 times the estimate. Large C.V.s alert the reader that the estimate has considerable variability. For purposes of this study, an estimate was considered to have large variability if its C.V. was greater than 30 percent.

NEISS Results

From 1995 to 2003 inclusive, there were an estimated 16,712 injuries associated with drain openers treated in U.S. hospital emergency rooms. Table 1 shows the annual estimates along with their associated coefficients of variation. No yearly trend was identified.

Table 1: Estimated number of emergency-room treated injuries associated with drain openers by year, 1995-2003

Year	Estimated Number of Injuries	Coefficient of Variation
1995	1,298	0.16
1996	1,509	0.20
1997	2,183	0.21
1998	2,553	0.17
1999	1,716	0.23
2000	2,110	0.24
2001	1,835	0.19
2002	1,655	0.17
2003	1,853	0.19
Total	16,712	0.09

Source: National Electronic Injury Surveillance System, Directorate for Epidemiology, U.S. Consumer Product Safety Commission.

A breakdown of the data from 1995 to 2003 according to type of drain opener is shown in Table 2. Most of the cases involved drain openers of unknown composition. Of those injuries where the

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¹ For a full discussion of the adjustment methodology, see Marker et al., 1999, listed in the references section of this report.

type of drain opener was known, ten percent involved sulfuric acid drain openers, and 68 percent involved alkaline drain openers.

The 1,402 injuries involving mixtures included situations in which drain openers were mixed with a wide variety of other substances. The most common was bleach. While a few mixtures were of an alkaline substance combined with an acid drain opener, mixtures of alkaline drain openers and SADOs were relatively rare.

Table 2: Estimated number of emergency-room treated injuries associated with drain

openers by drain opener type, 1995-2003

Drain Opener Type	Estimated Number of Injuries	Coefficient of Variation
Sulfuric acid	768	0.25
Alkaline	5,318	0.12
Mixtures	1,402	0.18
Other*	299	0.40
Unknown	8,925	0.13
Total	16,712	0.09

^{*}includes hydrochloric acid, acids of unknown type, and enzyme-based drain openers. C.V. is large.

Source: National Electronic Injury Surveillance System, Directorate for Epidemiology, U.S. Consumer Product Safety Commission.

The distribution by age of injuries associated with drain openers is given in Table 3. The age group accounting for the largest portion of injuries was the 36- to 45-year-old age group, which accounted for 19 percent of the injuries. Also notable were the injury estimates for the 0- to 5-year-old age group and the 26- to 35-year-old age group.

Table 3: Estimated number of emergency-room treated injuries

associated with drain openers by age group, 1995-2003

	Estimated Number
Age Group	of Injuries
0 to 5 years	2,852
6 to 15 years	980
16 to 25 years	2,207
26 to 35 years	2,824
36 to 45 years	3,210
46 to 55 years	1,623
56 to 65 years	1,678
66 to 75 years	937
76 years and up*	401
Total	16,712

^{*} C.V. is large.

Source: National Electronic Injury Surveillance System, Directorate for Epidemiology, U.S. Consumer Product Safety Commission.

Table 4 below shows the diagnoses of the 16,712 injuries. Chemical burns made up nearly half of the diagnoses. Almost a third of the chemical burns (2,598 of 8,260) were to the eyeball. About the same proportion (5,125 of 16,712) of all injuries were to the eyeball. The "other"

category includes ingestion of foreign object, foreign body, laceration, other and unknown diagnoses.

Table 4: Estimated number of emergency-room treated injuries associated with drain openers by diagnosis, 1995-2003

Diagnosis	Estimated Number of Injuries
Chemical burns	8,260
Anoxia*	482
Poisoning	4,033
Dermatitis, Conjunctivitis	1,816
Contusions/Abrasions*	581
Other	1,541
Total	16,712

^{*} C.V. is large.

Source: National Electronic Injury Surveillance System, Directorate for Epidemiology, U.S. Consumer Product Safety Commission.

Most victims of injuries associated with drain openers were treated and released from the hospital emergency room, as shown in Table 5. A small portion (7 percent) were hospitalized.

Table 5: Estimated number of emergency-room treated injuries associated with drain openers by disposition, 1995-2003

Disposition	Estimated Number of Injuries
Treated and Released	15,502
Hospitalized	1,099
Other*	111
Total	16,712

^{*}Includes patients who left without being seen and patients with a disposition that was not stated. C.V. is large.

Source: National Electronic Injury Surveillance System, Directorate for Epidemiology, U.S. Consumer Product Safety Commission.

C. Exposures

TESS Data and Methodology

The American Association of Poison Control Centers (AAPCC) compiles information on all calls made to participating U.S. poison control centers through the Toxic Exposure Surveillance System (TESS). Participating poison control centers served 83 percent of the U.S. population in 1995 and 100 percent of the U.S. population in 2003 (Litovitz et al., 1996; Watson et al, 2004). Between three and four million people per year are poisoned in the U.S., and TESS captures data on about 2.4 million of these poisonings (Miller et al, 1997; Watson et al, 2004). National Health Interview Survey data shows that poisonings of young children are reported to poison control

centers 79 percent of the time (Polivka et al, 2002). Because of this, the counts of poison exposures presented here should be regarded as undercounts of the number of exposures to drain openers. CPSC purchases TESS data from AAPCC on exposures of children under five years old to household products and medicines, as part of CPSC's administration of the Poison Prevention Packaging Act.

While CPSC does not purchase adult TESS data, the set of pediatric data that is available is a rich source of information that may provide insight into exposures of children under five to drain openers. TESS cannot be used to analyze trends because of changing center participation from year to year and other factors (Watson et al., 2003). However, analysis of pediatric TESS data in the aggregate can shed light on the scenarios associated with and the effects of children's contact with drain openers.

Pediatric TESS data in five substance codes were examined. The five codes were 0201006 (drain cleaners: sulfuric acid), 0201005 (drain cleaners: hydrochloric acid), 0011289 (drain cleaners: alkali), 0115287 (drain cleaners: other/unknown acid), and 0077314 (drain cleaners: other/unknown). Only general unintentional exposures were included. Drain cleaner exposures concomitant with exposures to other substances were not included. In 2000, acid drain cleaners were not coded by subcategory (sulfuric, hydrochloric or other). After 2000, acid drain openers were further categorized as hydrochloric, sulfuric or acid: other/unknown. Because of this coding change, the data were systematically searched by CPSC Health Sciences staff, who recoded or verified the drain cleaner type based on information in the record.

TESS aggregate data from several AAPCC annual reports have also been used in this report to give a picture of overall drain opener exposures to all ages. The 1995-2003 annual reports were used to produce tables of all drain cleaner exposures reported. (Litovitz et al., 1996; Litovitz et al., 1997; Litovitz et al., 1998; Litovitz et al., 1999; Litovitz et al., 2000; Litovitz et al., 2001; Litovitz et al., 2002; Watson et al., 2003; and Watson et al., 2004). The all-ages tables follow the pediatric tables.

It should be noted that TESS data represent only exposures resulting in calls to poison control centers participating in TESS. Generalizations made to any larger populations should be made with caution and with the limitations of the data in mind. A variety of differences in the distributions of TESS data and any larger populations may exist.

TESS Results: Children Under Five

A total of 1,956 unintentional drain cleaner exposures to children under five were identified through TESS for the period 2000 to 2002. Most victims (56 percent) were males. Sixty-six percent were one- or two-year-olds. Table 6 gives the distribution of exposures by drain cleaner type. Sulfuric acid drain cleaners constitute about five percent of the total. It should be noted that the alkaline category may include products with a wide range of hydroxide concentrations (e.g., 2-40 percent for liquids; 60-100 percent for granular formulations). The likelihood and severity of injury resulting from exposure to alkaline products depends in part on the hydroxide concentration (Brundage, 2005).

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Table 6: Exposures to drain cleaners of children under five years old by type, 2000-2002

Drain Cleaner Type	Number of Exposures
Alkaline	1,363
Enzyme/other	153
Sulfuric acid	96
Hydrochloric acid	52
Unknown	292
Total	1,956

Sources: American Association of Poison Control Centers TESS file and

U.S. Consumer Product Safety Commission.

Exposure sites for all drain cleaners were distributed among the victim's own residence, other residence, workplace, school, public areas, other and unknown locations. A large portion (96 percent) of the exposures to any drain cleaner type occurred at the victim's own residence. Alkaline, hydrochloric acid, enzyme/other and unknown drain cleaners all displayed a distribution of exposure site that showed at least 95 percent of the exposures occurring in the victim's own residence. Eighty-two percent of the sulfuric acid drain cleaner exposures occurred at the victim's residence, while 14 percent occurred at areas classified in TESS as "other." However, the 14 percent were all inhalation injuries resulting from the same incident.

The route of exposure for the 1,956 cases is given in Table 7 below. The possibilities for the coding of route of exposure are listed in Appendix A. Children may have been exposed by more than one route, and multiple routes were coded in those cases. The "other routes" category includes exposures by the aspiration, parenteral, other and unknown routes.

Table 7: Exposures to drain cleaners of children under five years old by route of exposure

and drain cleaner type, 2000-2002

D .	A 11 12	E	Sulfuric Acid	Hydrochloric Acid	Unknown	Total
Route	Alkaline	Enzyme/Other	Acid			
Ingestion	1,036	132	30	38	201	1,437
Dermal	454	34	50	12	104	654
Inhalation	45	0	26	5	18	94
Ocular	51	7	6	3	11	78
Other routes	9	1	1	0	2	13_

Sources: American Association of Poison Control Centers TESS file and U.S. Consumer Product Safety Commission.

The sulfuric acid category is the only one for which more dermal exposures than ingestions were reported. In addition, nearly three-fourths of the SADO dermal exposures (37 of 50) were single-route exposures, compared to 52 percent (234 of 454) of the alkaline dermal exposures. Sixty-seven percent (20 of 30) of the SADO ingestions were single-route exposures, compared to eighty percent (825 of 1,036) of alkaline ingestions.

Only nine SADO cases (nine percent of the total of 96) occurred by both routes, while 206 alkaline cases (15 percent of the total of 1,363) occurred by both routes. For the 2000-2002 period, sulfuric acid drain opener exposures reported to TESS clearly exhibit a different

distribution of exposure route than the exposures to other types of drain openers reported to TESS for children under five.

The occurrence of clinical effects is shown in Table 8. Fifty-five percent of the SADO exposure cases reported to TESS exhibited clinical effects, compared to 42 percent of the alkaline exposure cases.

Table 8: Exposures to drain cleaners of children under five years old by clinical effects and drain cleaner type, 2000-2002

Drain Cleaner Type	Number exhibiting clinical effects	Percent exhibiting clinical effects	Total
Alkaline	566	42	1,363
Enzyme/other	24	16	153
Sulfuric acid	53	55	96
Hydrochloric acid	9	17	52
Unknown	138	47	292
Total	790	40	1,956

Sources: American Association of Poison Control Centers TESS file and U.S. Consumer Product Safety Commission.

The 790 victims in the above table exhibited clinical effects that were dermal (409), gastrointestinal (368), ocular (68), respiratory (49), neurological (15) and cardiovascular (1) in nature. These counts are not mutually exclusive; victims could have experienced effects in more than one clinical effect group. Interestingly, while 73 percent of the exposures occurred by the ingestion route (Table 7), only 43 percent of the victims experienced gastrointestinal clinical effects.

Table 9: Exposures to drain cleaners of children under five years old by medical outcome

and drain cleaner type, 2000-2002

	5) P 5) = 5 5 5		Sulfuric	Hydrochloric		
Medical Outcome	Alkaline	Enzyme/Other	Acid	Acid	Unknown	<u>Total</u>
None	428	56	26	23	85	6.18
Minor	342	16	23	6	83	470
Moderate	133	3	14	1	35	186
Major	16	0	3	1	4	24
Not followed, nontoxic effect	75	16	3	5	12	111
Not followed, minimal effects	304	58	18	12	55	447
Unable to follow, toxic effect	39	0	7	1	14	61
Unrelated effect	26	4	2	3	4	39
Total	1,363	153	96	52	292	1,956

Sources: American Association of Poison Control Centers TESS file and U.S. Consumer Product Safety Commission.

Medical outcome of the 1,956 exposure cases is presented in Table 9. In the first four categories, cases were followed at least until outcome could be definitively determined. Twenty-four cases

were confirmed to have experienced a major effect, defined as life-threatening or resulting in significant residual disability or disfigurement. Moderate outcomes are defined in TESS as having more pronounced, prolonged or systemic symptoms than minor cases. Moderate outcomes are cases that were not life-threatening, and the patient had no residual disability or disfigurement, but usually some form of treatment is indicated. These moderate outcomes accounted for 186 cases. Cases that were not followed but were judged as potentially toxic, resulting in a moderate or major outcome, numbered 61. In all, 271 cases (14 percent of the total) were confirmed or judged to have been toxic exposures resulting in a moderate or major outcome. There were no fatalities in this age group for the years examined.

For the years 2000-2002, one-fourth (24 of 96) of the sulfuric acid drain opener exposures to children under five were confirmed or judged as potentially toxic, resulting in moderate or major outcomes, while 14 percent (188 of 1,363) of alkaline exposures fell in the same categories. As previously noted, the alkaline category may include products with a wide range of hydroxide concentrations, and these concentrations may affect the likelihood and severity of injury associated with them. (Brundage, 2005).

See Appendix A for definitions of medical outcomes.

TESS Results: All Ages

The American Association of Poison Control Centers publishes aggregate statistics on drain opener exposures reported through TESS in its annual report. From 1995 to 2003 AAPCC reported 48,700 exposures to drain openers involving victims of all ages. Until 2000 drain opener exposures were classified in TESS only as alkali, acid or other/unknown. Since 2001, acid drain opener exposures have been further subcategorized as hydrochloric, sulfuric or acid: other/unknown. Combined totals for the years 1995 through 2003 are shown in Table 10. The acid category includes cases coded as any type of acid drain cleaner. The pediatric exposures in Tables 6-9 are included in Tables 10-13.

Table 10: Exposures to drain cleaners by type and year, all ages, 1995-2003

Year	Acid	Alkali	Other/unknown	Total
1995	938	3,447	397	4,782
1996	939	3,769	406	5,114
1997	1,078	3,816	483	5,377
1998	1,056	4,112	470	5,638
1999	1,143	4,204	552	5,899
2000	1,009	3,890	460	5,359
2001	959	3,861	708	5,528
2002	984	3,747	756	5,487
2003	739	4,019	758	5,516
Total	8,845	34,865	4,990	48,700

Sources: Litovitz et al., 1996; Litovitz et al., 1997; Litovitz et al., 1998; Litovitz et al., 1999; Litovitz et al., 2000; Litovitz et al., 2001; Litovitz et al., 2002; Watson et al., 2003; Watson et al., 2004

Note: TESS data cannot be used to analyze trends because of changing participation by individual poison control centers and other factors.

TESS cannot be used to analyze trends in the number of exposures over time because of fluctuation in poison control center participation in TESS. In addition, AAPCC instituted a national 800 poison control telephone number in late 2000 that may have affected the number of calls to poison control centers. However, several observations can be made about the yearly totals. While the acid category shows an apparent decrease in the early 2000s, the total does not show the same decrease. It may be that more acid drain openers were coded in the other/unknown category during these years than had been the case in the late 1990s, before there were separate categories for sulfuric and hydrochloric acid drain openers.

Eighteen percent of the 48,700 drain opener exposures were classified as acid. For 2001 through 2003, sulfuric acid drain openers constituted 54 percent of the acid categories, or 8.8 percent of all drain opener exposures reported to TESS.

Not all of the exposures reported through TESS during 1995 to 2003 were unintentional. Ingestion of drain openers has been used as a method of suicide, and these suicides and similar non-fatal attempts are often reported through TESS. In addition, some drain openers have been used to make homemade bombs. In fact, the same ingredients that allow some drain openers to be used for this purpose are also used in the manufacture of fertilizers, another common ingredient of homemade bombs. (Hardin et al., 2003). Because they come from AAPCC annual reports, the statistics presented here on drain openers for all ages include intentional and malicious incidents.

While CPSC staff does not have resources readily available for a case-by-case examination in order to eliminate those intentional incidents, figures on intent for the group of drain opener exposures as a whole are available. Table 11 presents figures for the unintentional exposures during 1995 to 2003. Ninety-three percent of the total were unintentional.

Table 11: Exposures by drain opener type and intent, all ages, 1995-2003

Drain Opener Type	All Exposures	Unintentional Exposures
Acid	8,845	8,372
Alkali	34,865	32,332
Other/Unknown	4,990	4,657
Total	48,700	45,361

Sources: Litovitz et al., 1996; Litovitz et al., 1997; Litovitz et al., 1998; Litovitz et al., 1999; Litovitz et al., 2000; Litovitz et al., 2001; Litovitz et al., 2002; Watson et al., 2003; Watson et al., 2004

The TESS figures reported in the unintentional exposure column differ from NEISS injury estimates in part because not all exposures reported to poison control centers are treated in hospital emergency rooms. TESS does collect data on whether the exposed victim was treated in a health-care facility, however. These health care facilities may be hospital emergency rooms, clinics, physicians' offices, or some other health care site.

Table 12: Exposures by drain opener type and treatment in a health care facility, all ages, 1995-2003

Drain Opener Type	All Exposures	Treated in a Health Care Facility
Acid	8,845	3,173
Alkali	34,865	11,442
Other/Unknown	4,990	1,238
Total	48,700	15,853

Sources: Litovitz et al., 1996; Litovitz et al., 1997; Litovitz et al., 1998; Litovitz et al., 1999; Litovitz et al., 2000; Litovitz et al., 2001; Litovitz et al., 2002; Watson et al., 2003; Watson et al., 2004

As shown, 33 percent of all drain opener exposures reported through TESS were treated in health care facilities. When only acid drain openers are examined, 36 percent were treated in health care facilities, while 33 percent of the alkali exposures reported through TESS were treated in health care facilities. These statistics may point toward a slightly greater severity of the injuries resulting from the exposures to acid drain openers reported through TESS for the specified years, or they may reflect a slightly stronger tendency among poison control center toxicologists to advise callers to take victims exposed to acid drain openers to health care facilities. However, as stated earlier, the alkaline category may include products with a wide range of hydroxide concentrations, and the concentration may affect the likelihood and severity of injury resulting from exposure to alkaline products (Brundage, 2005). If low-concentration products dominate the alkaline category, the differences in likelihood and severity of injuries between the alkaline and acid categories may be obscured.

The outcome of the 48,700 exposures in TESS is known in 60 percent (29,287 of the total) of the cases. Twenty-two percent (6,297 of 29,287) of these had no medical outcome. The distribution of medical outcomes of the 29,287 cases is shown in Table 13. See Appendix A for definitions of outcomes.

Table 13: Exposures by drain opener type and medical outcome, all ages, 1995-2003

Medical Outcome	Acid	Alkali	Other/Unknown	Total
None	912	4,581	804	6,297
Minor	3,059	11,074	1,351	15,484
Moderate	1,593	4,847	454	6,894
Major	70	437	35	542
Death	26	38	6	70
Total	5,660	20,977	2,650	29,287

Sources: Litovitz et al., 1996; Litovitz et al., 1997; Litovitz et al., 1998; Litovitz et al., 1999; Litovitz et al., 2000; Litovitz et al., 2001; Litovitz et al., 2002; Watson et al., 2003; Watson et al., 2004

Of the acid cases where outcome is known, 30 percent (1,689 of 5,660) experienced a moderate outcome or worse. Of the alkaline cases where outcome is known, 25 percent (5322 of 20,977) fell in the same categories. Fatalities accounted for 0.5 percent of the acid drain opener cases and

0.2 percent of the alkaline drain opener cases reported through TESS. Some of these deaths may be suicides.

A Closer Look: TESS Results for All Ages, 2001-2003

Closer examination of a subset of TESS data from 2001 to 2003 allows for breakdowns by more specific types of drain openers. After 2000, acid drain openers in TESS were coded as hydrochloric acid, sulfuric acid, or other/unknown acid. Table 14 presents this subset of data according to type and treatment in a health care facility.

Table 14: Exposures by drain opener type and treatment in a

health care facility, all ages, 2001-2003

Drain opener type	All Exposures	Treated in a Health Care Facility
Acid: hydrochloric	922	252
Acid: sulfuric	1,460	585
Acid: other/unknown	300	98
Alkaline	11,627	3,635
Other/unknown	2,222	552
Total	16,531	5,122

Sources: Litovitz et al., 1996; Litovitz et al., 1997; Litovitz et al., 1998; Litovitz et al., 1999; Litovitz et al., 2000; Litovitz et al., 2001; Litovitz et al., 2002; Watson et al., 2003; Watson et al., 2004

As can be seen from Table 14, 27 percent of the hydrochloric acid exposures reported to TESS from 2001 to 2003 were treated in health-care facilities. Forty percent of the sulfuric acid exposures reported through TESS were treated in health-care facilities, along with 31 percent of the alkaline exposures.

Table 15 below gives the distribution of types of drain openers by medical outcome. Twenty-six percent of the exposures to alkaline drain openers reported to TESS from 2001 to 2003 resulted in moderate or major outcomes or death, while 34 percent of the SADOs did. It should be noted that intentional incidents are included here.

Table 15: Exposures by drain opener type and medical outcome, all ages, 2001-2003

Medical Outcome	None	Minor	Moderate	Major	Death	Total
Acid: hydrochloric	120	332	119	9	1	581
Acid: sulfuric	123	513	305	16	5	962
Acid: other/unknown	20	110	45	2	1	178
Alkaline	1,464	3,445	1,553	168	16	6,646
Other/unknown	320	593	202	22	3	1,140
Total	2,047	4,993	2,224	217 1999: Litovitz et a	26	9,507

Sources: Litovitz et al., 1996; Litovitz et al., 1997; Litovitz et al., 1998; Litovitz et al., 1999; Litovitz et al., 2000; Litovitz et al., 2001; Litovitz et al., 2002; Watson et al., 2003; Watson et al., 2004

D. Deaths

Data Sources and Methodology

CPSC's Death Certificate database (DTHS) is a collection of death certificates purchased from the states. Death certificate reporting for 2000 through 2004 is still ongoing. The Injury and Potential Injury Incident database (IPII) is a collection of reports of deaths, injuries and some non-injury incidents that are reported to CPSC by way of the Internet, CPSC's hotline, the Medical Examiners' and Coroners' Alert Project, news clips, and various other means. At this writing, IPII collection for 2004 is also incomplete. Neither DTHS nor IPII constitute statistical samples and cannot be used to calculate estimates, but they can be used to generate a minimum count of deaths related to drain openers.

Deaths reported between January 1, 1995 and November 8, 2004 that were cataloged in DTHS or IPII were examined for this analysis. Duplicate reports were combined.

Results

CPSC is aware of six unintentional deaths associated with drain openers that were reported between January 1, 1995 and November 8, 2004, inclusive. All of the victims were adults except for a two-year-old boy who ingested an alkaline product.

Three of the six deaths involved mixtures that resulted in the inhalation of fumes. One of the mixtures was of a SADO and an alkaline product; another was an alkaline product and bleach; the third was a mixture of two drain openers of unknown type.

Two of the six deaths (including the two-year-old mentioned above) involved ingestion of single alkaline drain openers.

One death involved dermal exposure to an unknown type of drain cleaner. An elderly woman fell into spilled drain opener, suffered burns and died.

E. Discussion

From 1995 to 2003 there were 48,700 exposures to drain openers of all types (Table 10) reported through TESS. Unintentional exposures of children under five accounted for 12 percent of all TESS exposures from 2000 to 2002 (Tables 6 and 10).

Nine percent of all drain opener exposures reported to TESS in the period 2001-2003 were to SADOs (Table 14). This appears to be in line with the three- to ten-percent share of the retail chemical drain opener market claimed by SADOs (Franklin, 2005).

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NEISS data indicate that an estimated 16,712 injuries associated with drain openers were treated in hospital emergency rooms from 1995 to 2003 (Table 1). TESS captured slightly fewer (15,853) cases that were treated in health-care facilities that may have included emergency rooms, clinics, physicians' offices or other health-care sites (Table 12).

Fourteen percent (1,067 of 7,787) of the number of injuries estimated through NEISS associated with any type of drain opener where the drain opener type was known involved acids or enzymes (Table 2). Eighteen percent of the TESS exposures from 1995 to 2003 were to acid products (Table 10). The fact that there is a greater percentage of exposures (reported through TESS) than injuries (estimated by NEISS) associated with acids could mean that acid drain openers are less likely than other drain openers to cause injury. TESS data on medical outcomes do not support this conjecture (Table 13). The higher percentage representation of acids among exposures could also indicate that these products are easier to access than alkaline products, or that people are more likely to experience direct contact with the product in unexpected ways than is the case with alkaline drain openers. However, there are many drain openers of unknown type among the injuries, and any conclusions reached about the distribution of types of drain openers involved should be made with caution.

In the TESS data, children under five were more likely to be reported as being exposed to SADOs by a dermal route than by ingestion, and SADOs were the only drain opener type for which this was true (Table 7). Generally less than ten percent of all TESS exposures occur by a dermal route (Litovitz et al., 1996; Litovitz et al., 1997; Litovitz et al., 1998; Litovitz et al., 1999; Litovitz et al., 2000; Litovitz et al., 2001; Litovitz et al., 2002; Watson et al., 2003; Watson et al., 2004). Because of this, the high percentage of dermal exposures reported through TESS (52 percent, or 50 of the 96 SADO exposures) is noteworthy in this age group (Tables 6 and 7). When skin is exposed to an acid drain opener, the burn that results is felt immediately -faster than if exposed to an alkaline drain opener, which is associated with a delayed sense of irritation (Brundage, 2005). This may have limited the number of ingestions, if the victim experienced a dermal exposure to the acid while the acid was on the way to the victim's mouth. In other words, the experience of pain on the skin may have interrupted an ingestion in progress, before it occurred. Exposures to SADOs reported through TESS tended to be by a single exposure route in the under-five age group, and most were either ingestions or dermal exposures (page 7). The higher ratio of SADO dermal to ingestion exposures, compared to alkaline drain openers, could also be the result of the possibility that SADO ingestions might be easier to rule out when a child is discovered with a drain opener in hand. (Sedney, 2005). TESS data do not provide the detail necessary to determine if either of these conjectures is the case, or if the anomaly could have some other explanation.

TESS data also show that, in the pediatric group of cases examined, a greater percentage (55 percent) of SADO exposure cases experienced clinical effects than did alkaline exposure cases (42 percent) (Table 8). Similarly, 25 percent of SADO exposures reported through TESS resulted in moderate or worse outcomes, compared to 14 percent of alkaline cases (Table 9). Both of these comparisons may indicate that, during the period 2000 to 2002, calls reported to TESS involving exposure to SADOs were more likely to result in injuries of a more severe nature than calls involving exposure to alkaline drain openers, at least for the under-five age group. However, as noted earlier, the alkaline category may include products that are less likely to result

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in injury because of their low hydroxide concentration. The likelihood and severity of injury resulting from exposure to alkaline products depends in part on the hydroxide concentration (Brundage, 2005). In addition, the pediatric group may not share the same distribution of exposure routes, clinical effects and outcomes as all ages.

Among all ages, TESS data from 2001 to 2003 indicate that a higher percentage of reported SADO exposures was treated in health-care facilities than alkaline drain opener exposures (40 percent compared to 31 percent) (Table 14). Similarly, 34 percent of SADO exposures reported to TESS experienced a moderate or worse outcome, compared to 25 percent of alkaline exposures (Table 15). While the differences are not overwhelmingly large, these results lend support to the idea that sulfuric acid drain opener exposures reported to TESS from 2001 to 2003 were more likely to result in injuries of a more severe nature than exposures reported to TESS involving other drain openers. However, the alkaline category in both sets of data includes both low- and high-concentration alkalines. If there are differences in the severity of injuries associated with different concentrations of alkaline products, the predominance of low-concentration alkaline products in the data used for this analysis may obscure the differences or similarities between the high-concentration alkalines and the SADOs.

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Appendix A

Definitions of TESS Exposure Routes and Medical Outcomes

(AAPCC, 2002)

Exposure Routes

Aspiration: An exposure by the pulmonary route (tracheal). This route usually pertains to liquid or solid agents and occurs during or following an ingestion. If aspiration is coded, ingestion will automatically be coded. It is not an error to code both ingestion and aspiration.

Bite/sting: An exposure resulting from an animal/insect bite or sting with or without envenomation.

Dermal: An exposure involving the skin, hair, or fingernails.

Ingestion: An exposure by the oral route. Exposures in which the material was put in the mouth but unlikely to have reached the stomach should be classified as ingestions. Ingestions accompanied by aspiration are coded as aspirations. If aspiration is coded, ingestion will automatically be coded. It is not an error to code both ingestion and aspiration.

Inhalation/nasal: An exposure by the pulmonary route (tracheal or nasal). This route usually pertains to gaseous or vaporized agents.

Ocular: An exposure involving the eyeball.

Otic: An exposure to the ear or ear canal with or without perforation of the tympanic membrane (codeable only after 1999).

Parenteral: An exposure resulting from the injection of a substance into the body.

Rectal: An exposure involving the rectum where the implicated substance was physically placed in, applied to, or instilled in the rectum (codeable only after 1999).

Vaginal: An exposure involving the vagina where the implicated substance was physically placed in, applied to, or instilled in the vagina (codeable only after 1999).

Other: Any other route of exposure not listed above.

Unknown: The route of exposure is unknown.

Note: At least one route must be selected. Multiple routes may be selected.

Medical Outcomes

No Effect: The patient developed no signs or symptoms as a result of the exposure.

Minor Effect: The patient developed some signs or symptoms as a result of the exposure, but they were minimally bothersome, usually resolved rapidly, and usually involve skin or mucous membranes. The patient has no residual disability or disfigurement. Examples include minor gastrointestinal symptoms, skin irritation or first-degree burn, and drowsiness, among others.

Moderate Effect: The patient exhibited signs or symptoms as a result of the exposure that were more pronounced, more prolonged, or more of a systemic nature than minor symptoms. Symptoms were not life-threatening, and the patient has no residual disability or disfigurement. Usually some form of treatment is indicated. Examples include corneal abrasion, gastrointestinal symptoms causing dehydration, and high fever, among others.

Major Effect: The patient exhibited signs or symptoms as a result of the exposure that were life-threatening or resulted in significant residual disability or disfigurement. Examples include repeated seizures or status epilepticus, respiratory compromise requiring intubation, and ventricular tachycardia with hypotension, among others.

Death: The patient died as a result of the exposure or as a direct complication of the exposure where the complication was unlikely to have occurred had the toxic exposure not preceded the complication. Only those deaths which are probably or undoubtedly related to the exposure are coded here.

Unrelated Effect: The exposure was probably not responsible for the clinical effect.

Not followed, judged as nontoxic exposure: The patient was not followed because in the opinion of the poison control center, the exposure was likely to be nontoxic because the agent involved was nontoxic; the amount implicated in the exposure was insignificant (nontoxic); and/or the route of exposure was unlikely to result in a clinical effect.

Not followed, minimal clinical effects possible: The patient was not followed because in the opinion of the poison control center, the exposure was likely to result in only minimal toxicity of a trivial nature. No more than a minor effect will be experienced.

Unable to follow, judged as a potentially toxic exposure: The patient was lost to follow-up but the exposure was significant and may have resulted in toxic manifestations with a moderate, major or fatal outcome.

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TAB D

Memorandum

Date: July 28, 2005

To:

Kristina Hatlelid, Ph.D., M.P.H., Project Manager

Division of Health Sciences

Through:

Hugh McLaurin, Associate Executive Director

Directorate for Engineering Sciences

Robert B. Ochsman, Ph.D., Director

Division of Human Factors

From:

Catherine A. Sedney, Engineering Psychologist

Division of Human Factors

Subject:

Petition for a Ban of Sulfuric Acid Drain Openers for Consumer Use (CP 04-2)

Background .

Petition

In February of 2004, Michael Fox, Ph.D., petitioned the Commission to ban sulfuric acid drain openers as unreasonably dangerous for consumer use, or in the alternative, to require that they be packaged in "one-shot" containers and be limited to a maximum sulfuric acid concentration of 84 percent (69 FR 25069, May 5, 2004). The petitioner asserts that the Commission's 1996 denial of a similar request (HP 95-03) to ban these products was based on the inappropriate conclusion that they are no more hazardous than alkaline drain openers, and on an unwarranted reliance on the existence of a voluntary labeling standard.

This memorandum presents Human Factors staff assessment of the available information relevant to the petition, and addresses the following specific behavioral issues raised by the petitioner:

- That the number and severity of injuries involving alkaline drain cleaners reported in the incident data are inflated due to what the petitioner terms the "Kleenex Syndrome." Briefly, the petitioner believes that the brand name "Liquid Plumber" (sic) is used generically in reports of both alkaline and sulfuric acid drain opener incidents.
- That consumers splashed with sulfuric acid are helpless because they do not know how to respond, and labeling cannot address this hazard.

Product Information

Directorate for Economic Analysis (EC) staff describes the types and availability of chemical drain openers sold in the U.S. (Franklin, 2005). The most common drain openers are alkalis in liquid or granular form that contain sodium or potassium hydroxide. Liquids have hydroxide concentrations ranging from less than 2 percent to 40 percent; dry products have hydroxide concentrations ranging from 60 percent to near 100 percent. Familiar brand name dry products

and low-concentration liquid alkaline drain openers are sold in hardware and home center stores, but are also widely available in grocery, drug, and convenience stores. Liquids with higher concentrations are sold primarily in hardware and home center stores. Alkaline drain openers reportedly can be effective in dissolving clogs containing hair or grease.

Acid drain openers include those containing hydrochloric acid and those containing sulfuric acid. Sulfuric acid drain openers are commonly sold in hardware stores, and have concentrations ranging from 84 percent to 94 percent. Like alkaline drain openers, sulfuric acid products reportedly are effective at breaking up hair and grease clogs, but according to marketing claims, also can dissolve materials such as paper products and cloth. Hydrochloric acid products are potential substitutes if sulfuric acid drain openers were to be banned. Because the petition focuses on alkaline and sulfuric acid drain openers, only general information on hydrochloric acid will be presented. Drain openers containing hydrochloric acid range in concentration from 5 percent to 30 percent (Franklin, 2005). Hydrochloric acid drain openers may effectively treat hair and grease clogs, but are also used to break down mineral deposits and substances such as concrete, plaster, and grout.

Both alkaline and acid products are regulated under the Poison Prevention Packaging Act (PPPA) and the Federal Hazardous Substances Act (FHSA). Household substances in dry forms containing 10 percent or more by weight of free or chemically unneutralized sodium and/or potassium hydroxide, and all other household substances containing 2 percent or more by weight of free or chemically unneutralized sodium and/or potassium hydroxide, must be sold in child-resistant packaging [16 CFR §1700.14(a)(5)]. Household substances containing 10 percent or more by weight of sulfuric acid, except such substances in wet-cell storage batteries also require child-resistant packaging [16 CFR §1700.14(a)(9)]. Substances containing free or chemically unneutralized hydrochloric acid, sulfuric acid, potassium hydroxide, or sodium hydroxide in concentrations of 10 percent or more require the signal word "POISON" [16 CFR 1500.129 (a), (b), (i), and (j)].

Injury Potential of Acid and Alkaline Drain Openers

Health Sciences (HS) staff (Brundage, 2005) provided a detailed review of the type, extent, and treatment of injuries caused by alkaline and acid drain openers. Hazardous exposures can occur with acids and alkalis via ingestion and contact with the skin or eyes. Additionally, exposure via inhalation is possible with acids because they can form a mist. Of the acids, hydrochloric acid is less vigorous than sulfuric acid, but still can cause significant injury. Damage to dermal tissue occurs more rapidly with sulfuric acid at high concentrations than with alkalis. Another important difference between them is the sensation they produce on contact with the skin. In a small study (n=3) cited by HS staff (Davidson, 1927), response latency to 96 percent sulfuric acid applied to the skin was 4 seconds, and to a 50 percent concentration, was 50 seconds. In contrast, 50 percent sodium and potassium hydroxide on the skin for three minutes induced no sensation. As a result, it is possible that washing may be delayed with alkaline drain openers. HS staff concluded that, although the mechanism of injury differs between them, both types are hazardous and can cause injuries ranging from minor to fatal depending on the concentration, pH, and amount of the chemical involved, as well as the type of tissue exposed and the duration of contact.

Incident Data

The petitioner identifies a single incident in which a bottle of sulfuric acid drain opener fell from a shelf above a woman who was holding a child. The bottle spilled, apparently with most of the product falling on the child. The information provided suggests that initially no attempt was made to wash off the acid from either victim. When emergency medical personnel arrived, they responded incorrectly by using small amounts of saline solution a little at a time to wash the child. No further information was provided regarding the injuries of the adult. The child's injuries, aggravated by inappropriate treatment, were extensive and disfiguring.

Epidemiological Analysis

Hazard Analysis (HA) staff (Ingle, 2005) analyzed death, injury, and incident reports contained in Commission databases, and poison exposure data from the Toxic Exposure Surveillance System (TESS).

Deaths

HA identified six unintentional deaths involving drain openers that occurred between January 1, 1995 and November 8, 2004, in CPSC's Injury and Potential Injury Incidents (IPII) and Death Certificates (DTHS) databases. Two of the deaths, including that of a two-year-old boy, resulted from ingestion of an alkaline drain opener. Three were caused by inhalation of fumes from mixtures of products (acid and alkali, alkali and bleach, and two unknown products). The remaining death, in which an elderly woman fell into spilled drain cleaner of an unknown type, involved dermal contact. HA staff notes that these data represent a minimum count of deaths related to drain openers; because the IPII and DTHS databases are not statistical samples, they cannot be used to calculate estimates.

NEISS

The National Electronic Injury Surveillance System (NEISS) is based on a representative sample of hospitals in the U. S. and its territories. The data are drawn from medical records of emergency room visits associated with use of consumer products. It excludes intentional and occupational incidents. HA staff identified 522 incidents reported through NEISS involving drain openers, and provided national estimates of the frequency of such incidents. Cases were reviewed by HA and HS staff to identify the type of drain opener product or products involved (i.e., alkali, hydrochloric acid, sulfuric acid, mixtures of drain openers or drain openers with other products, and drain openers of unknown type).

For the years 1995 through 2003, HA reports that there were an estimated 16,712 consumer-related visits to emergency rooms associated with drain openers of all types (annual average=1857). The tables below, adapted from Ingle (2005, Table 2), present the percentage of incidents by product type. Note that in a large percentage of cases, the drain opener was coded as unknown. The breakdown of consumer visits to emergency rooms in Table 1a includes the unknown category; Table 1b presents the percentages in each category for which the type of drain opener was known.

Table 1a. NEISS: Estimated Percentage of Cases by Product Type, 1995 through 2003¹

		Product Type		
Alkali	Sulfuric Acid	Mixtures	Unknown	Other*
32%	5%	8%	53%	2%

N=16,712

Sources: National Electronic Injury Surveillance System, Directorate for Epidemiology, Division of Human Factors, U.S. Consumer Product Safety Commission.

Table 1b. NEISS: Estimated Percentage of Cases by Product Type, Unknown Cases Excluded, 1995 through 2003²

Product Type					
Alkali	Sulfuric Acid	Mixtures	Other*		
68%	10%	18%	4%		

N=7,854

Seventeen percent of cases involved children five years of age and younger, and 56 percent involved adults aged 26 to 65. About half of all cases were diagnosed as chemical burns; the remaining cases, in order of frequency, were reported as poisoning, dermatitis/conjunctivitis, other (ingestion of foreign object, foreign body, laceration, other and unknown) and contusions/abrasions. Over 90 percent of consumers were treated and released or examined and released without treatment. Seven percent were hospitalized.

TESS: All Ages and Children under Five

The TESS database consists of detailed records based on calls to participating poison control centers in the U.S. and compiled by the American Association of Poison Control Centers (AAPCC). The AAPCC produces annual reports that summarize TESS data, which, although the proportions are small, include intentional, malicious, and work-related incidents. HA and HS analyzed the TESS data on drain opener exposures for all age groups as presented in the AAPCC annual reports for two periods, 1995 through 2003, and 2001 through 2003. The two periods were examined separately because of coding changes in the TESS database. For years through 2000, drain opener exposures were categorized only as acid, alkali, and other/unknown. Since 2001, the TESS classification of drain opener exposures has included sulfuric acid, hydrochloric acid, and other/unknown acid as separate categories. The percentage of incidents in each category for the two periods, adapted from the HA staff memo, are presented in Table 2 (Ingle, 2005; Table 10) and Table 3 (Ingle, 2005; Table 14) below. For the years 1995 through 2003, the TESS database included 48,700 drain opener exposures in

^{*}Includes hydrochloric acid, acids of unknown type, and enzyme-based drain opener. HA staff notes that this estimate is considered to have large variability (i.e., coefficient of variation >.30).

^{*}Includes hydrochloric acid, acids of unknown type, and enzyme-based drain opener. HA staff notes that this estimate is considered to have large variability (i.e., coefficient of variation > .30).

Sources: National Electronic Injury Surveillance System, Directorate for Epidemiology, Division of Human Factors, U.S. Consumer Product Safety Commission.

¹ Table 2, Ingle, 2005.

² Table 2, Ingle, 2005.

³ The reader is directed to Ingle, 2005 for full citations of these reports.

these categories: 72 percent alkali, 18 percent acid, and 10 percent other/unknown. For 2001 through 2003, alkaline products were associated with approximately 70 percent of drain opener exposures, while sulfuric acid accounted for about 9 percent.

Table 2. TESS/All Ages: Percentage of Exposures by Product Type for 1995 through 2003⁴

	Product Type	
Alkali	All Acid	Other/Unknown
72%	18%	10%
N=48,700 Sources: American As Consumer Product Sa Epidemiology, Division	ssociation of Poison C fety Commission, Dire	ontrol Centers; U.S. ectorate for

Table 3. TESS/All Ages: Percentage of Exposures by Product Type, 2001 through 2003⁵

Product Type						
Alkali Sulfuric Ad		Hydrochloric Acid	Other/Unknown Acid	Other/Unknow		
70%	9%	6%	2%	13%		

N=16,531

Sources: American Association of Poison Control Centers; U.S. Consumer Product Safety Commission Directorate for Epidemiology, Division of Human Factors.

Follow-up data reported in TESS include whether the victim received treatment at a medical facility (e.g., a hospital, clinic or doctor's office), and thus may capture incidents requiring treatment that are not included in NEISS. HA reports that in the TESS data for 1995 through 2003, 36 percent of victims exposed to drain openers containing some type of acid were treated at a health care facility, versus 33 percent for victims of alkali exposure (Table 12, Ingle, 2005). Medical outcomes were known⁶ in 60 percent of cases for this period. The percentage of cases in each of the five known outcome categories for alkali, acid, and other/unknown types of drain openers, derived from data presented by HA staff (Table 13, Ingle, 2005), are presented in Table 4.

⁴ Table 10, Ingle, 2005.

⁵ Table 14, Ingle, 2005

⁶ For drain openers, only confirmed known outcomes, categorized as "None," "Minor," "Moderate," and "Death," are included in the AAPCC Annual Reports from which these data are drawn. Unknown outcomes comprise the following four unreported categories: (1) exposures that were not followed because the effect was judged as likely to be nontoxic; (2) exposures that were not followed because the effects were judged as likely to be minimal; (3) exposures that could not be followed, but were judged as potentially toxic, and may have resulted in a moderate, major or fatal outcome; (4) effects reported that were judged as likely to be unrelated to the exposure.

Table 4. TESS/All Ages: Medical Outcomes for Alkaline, All Acid, and Other/Unknown Drain Openers 1995-2003⁷

	Outcome					
Product Type	None	Minor	Moderate	Major	Death	
Alkali (n=20,977)	21.8%	52.8%	23.1%	2.1%	0.2%	
All Acid (n=5,660)	16.1%	54.0%	28.1%	1.2%	0.5%	
Other/Unknown (n=2,650)	30.3%	51.0%	17.1%	1.3%	0.2%	

Note: Outcomes defined as minor are those in which the signs or symptoms of exposure are minimally bothersome, usually resolve rapidly, and involve no residual disability or disfigurement. Moderate effects are more pronounced, more prolonged, or of a more systemic nature than minor symptoms, and some form of treatment is usually indicated. The symptoms are not life-threatening and result in no residual disability or disfigurement. Major outcomes are considered life-threatening or result in significant residual disability or disfigurement. Verbatim definitions of outcomes are provided in Appendix A, Ingle 2005.

Note: Rows may not sum to 100% due to rounding.

Sources: American Association of Poison Control Centers; U. S. Consumer Product Safety Commission, Directorate for Epidemiology, Division of Human Factors.

As noted above, for the years 2001 through 2003, acid drain openers were coded by subcategory in the TESS database. HA reports that for this period, 40 percent of those exposed to sulfuric acid drain openers were treated in a medical facility, versus 31 percent of those exposed to alkaline drain openers (Table 14, Ingle 2005). Medical outcome for the various drain opener types for this period, derived from data provided by HA staff (Table 15, Ingle, 2005) is presented in Table 5.

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⁷ Table 13, Ingle, 2005.

Table 5. TESS/All Ages: Medical Outcomes For Drain Openers Classified As Sulfuric, Hydrochloric, Or Other/Unknown Acid, Alkaline, And Other/Unknown Drain Openers (2001-2003)8

			Outcome	1	
Product Type	None	Minor	Moderate	Major	Death
Alkali (n=6,646)	22.0%	51.8%	23.4%	2.5%	0.2%
Sulfuric Acid (n=962)	12.8%	53.3%	31.7%	1.7%	0.5%
Hydrochloric Acid (n=581)	20.7%	57.1%	20.5%	1.5%	0.2%
Other/Unknown Acid (n=178)	11.2%	61.8%	25.3%	1.1%	0.6%
Other/Unknown (n=1,140)	28.1%	52.0%	17.7%	1.9%	0.3%

Note: Outcomes defined as minor are those in which the signs or symptoms of exposure were minimally bothersome, usually resolved rapidly, and involved no residual disability or disfigurement. Moderate effects were more pronounced, more prolonged, or of a more systemic nature than minor symptoms, and some form of treatment is usually indicated. The symptoms are not life-threatening and result in no residual disability or disfigurement. Major outcomes are considered life-threatening or resulted in significant residual disability or disfigurement. Verbatim definitions of outcomes are included in Appendix A, Ingle 2005.

Note: Row totals may not equal 100% due to rounding.

Sources: American Association of Control Centers; U.S. Consumer Product Safety Commission Directorate for Epidemiology, Division of Human Factors.

Unlike the exposure data for all age groups, which is drawn from the AAPCC's annual reports, CPSC purchases TESS data for children under five years of age as part of its administration of the Poison Prevention Packaging Act (Ingle, 2005). This analysis excludes intentional exposures and exposures to drain openers in combination with some other substance, and includes more detailed outcome data than are available in the annual reports.

HA and HS examined TESS data on drain opener exposures for children under five for the years 2000 through 2002 (Ingle, 2005).9 Note that the drain opener categories differ somewhat from those used for exposures among all age groups. As shown in Table 6, which is based on data presented by HA (Ingle, 2005), 70 percent of exposures were coded as alkalis, 5 percent

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⁸ Table 15, Ingle, 2005.

⁹ Because drain opener exposures prior to 2001 were coded only as alkali, acid, or other/unknown, HS staff examined these data records for the year 2000 to verify the product and recoded acid-related incidents by type (sulfuric, hydrochloric, other/unknown acid) for consistency with the classification of drain opener exposure data for 2001 through 2002.

Table 6. TESS/Children under Five: Percentage of Exposures by Product Type, 2000 through

	. `	Product Type	· *	
Alkali	Sulfuric Acid	Hydrochloric Acid	Enzyme/Other	Unknown
70%	5%	3%	8%	15%

N=1956

Note: Row totals may not equal 100% due to rounding.

Sources: American Association of Poison Control Centers; U.S. Consumer Product Safety Commission Directorate for Epidemiology, Division of Human Factors.

as sulfuric acid, 3 percent as hydrochloric acid, 8 percent as enzymes or other, and 15 percent as unknown. Exposures among children under five occurred almost exclusively in residential settings.

Medical outcomes for cases in this age group involving sulfuric acid exposure and alkali exposure, adapted from data presented by HA (Table 9, Ingle, 2005), are shown in Table 7. HA reports that in the pediatric data (i.e., exposures involving children younger than five) purchased by CPSC, there were no "general unintentional" deaths related to acute exposure to drain openers (R. Ingle, personal communication, 2-22-2005). As described by HA, exposures in which the outcomes were categorized as None, Minor, Moderate, or Major are those cases that were followed until an outcome was definitive. In the remaining categories are those exposures that were not or could not be followed, and based on the information available, the effects were judged to be nontoxic; minimal; toxic with the potential for moderate, major, or fatal effects; or unrelated to the reported exposure. 11 HA notes that of cases involving sulfuric acid exposure, 25 percent resulted in outcomes confirmed or judged to be moderate or major as defined in the table notes, versus 14 percent for exposures to alkaline drain openers.

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¹⁰ Table 6, Ingle, 2005.

¹¹ See Ingle, 2005, Appendix A, for verbatim definition of medical outcomes.

Table 7. TESS/Children under Five: Percentage of Exposures by Medical Outcome, 2000 through 2002¹²

			-	Outcome	ė		. •	
Product Type	None	Minor	Moderate	Major	Not Followed Nontoxic Effect	Not Followed Minimal Effects	Unable to Follow, Toxic Effect	Unrelated Effect
Alkali (n=1363)	31%	25%	10%	1%	6%	22%	3%	2%
Sulfuric Acid (N=96)	27%	24%	15%	3%	3%	19%	7%	2%

Note: Outcomes defined as minor are those in which the signs or symptoms of exposure were minimally bothersome, usually resolved rapidly, and involved no residual disability or disfigurement. Moderate effects were more pronounced, more prolonged, or of a more systemic nature than minor symptoms, and some form of treatment is usually indicated. The symptoms are not life-threatening and result in no residual disability or disfigurement. Major outcomes are considered life-threatening or resulted in significant residual disability or disfigurement. Verbatim definitions of outcomes are included in Appendix A, Ingle, 2005.

Note: Row totals may not equal 100% due to rounding.

Sources: American Association of Control Centers; U.S. Consumer Product Safety Commission, Directorate for Epidemiology, Division of Human Factors.

Among the variables HA examined in the TESS data for children under five was the route or routes by which the exposure occurred (e.g., ingestion, ¹³ dermal, ocular, ingestion and dermal, ingestion and ocular, etc.). HA reports that sulfuric acid was the only drain opener type for which there were more dermal exposures than ingestions. Among the reported exposures of children under five, dermal contact was more likely when the product involved was a sulfuric acid drain opener than when any other type of drain opener was involved. When all cases that included dermal contact are considered, the percentage coded as dermal-only was larger among sulfuric acid exposures than among alkali exposures (74 percent v. 52 percent; p. 8, Ingle, 2005). Among exposures that included ingestion, the percentage coded as ingestion-only was higher among those involving alkalis than among those involving sulfuric acid (80 percent v. 67 percent; p. 8, Ingle, 2005). As a percentage of the total exposures in each of these two categories of drain opener, the percentage involving both dermal contact and ingestion was lower among sulfuric acid exposures than among alkali exposures (9 percent v. 15 percent; p. 8, Ingle, 2005).

It is not clear that these results, either for all ages, or for children under five, definitively support the petitioner's claim that exposures to sulfuric acid drain openers necessarily result in more severe injuries than do exposures to alkaline products. First, alkaline drain openers vary much more widely in concentration, as well as availability, than do sulfuric acid products. EC staff has identified liquid alkaline drain opener products with sodium hydroxide concentrations that may range from as low as 0.5 percent (R. Franklin, personal communication, May 24, 2005) to a high of 40%, with low concentration brands making up the largest proportion of the market. Because concentration is an important factor affecting injury potential (Brundage, 2005), the differences in outcome for the different product types (Ingle 2005; shown here in Tables 5 and 7) are confounded by the broad range of concentrations among alkaline drain openers. Thus, the data

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¹² Table 9, Ingle, 2005.

¹³ Ingestion is defined as exposure by the oral route regardless of the likelihood that the substance reached the stomach (Appendix A, Ingle, 2005).

may not accurately reflect the hazardousness of high concentration alkali-containing products that are the most likely substitutes for sulfuric acid drain openers.

Further, TESS is based on calls to poison control centers. Participating centers submit data on their calls to AAPCC for compilation, and participation varies to some extent. Although clearly a valuable resource, the TESS data may not be representative of exposures in general, and may differ from exposures that are not reported to a poison control center. For example, the latter may be less serious overall, and more easily resolved, or more serious, such that the exposed person is taken directly to a medical facility without a call to a poison control center. HA staff notes that the numbers of sulfuric acid exposures treated in medical facilities may reflect greater severity of injury, but it could also reflect a tendency of poison control center staff to recommend medical care for those exposed to sulfuric acid (Ingle, 2005). This could be related to the intensity of sensation elicited by sulfuric acid versus alkali contact, as described previously. The Material Safety Data Sheet (MSDS)¹⁴ for one concentrated hydroxide brand states, "...exposure can cause burns which are not immediately painful or visible..." In contrast, dermal contact with concentrated sulfuric acid reportedly causes a burning sensation within seconds (Davidson, 1927, cited in Brundage, 2005). Referral to a medical facility seems more likely if the exposed person, particularly a child, is in pain.

Similarly, the significance of the possible differences among children in exposure routes by type of drain opener is uncertain. Children often attempt to ingest household substances, and sometimes spill products on themselves in the process. Thus, it is interesting that in the TESS database, reports of dermal exposures, suggesting spills and other types of product interaction that might result in skin contact, were proportionally higher than reports of ingestion for sulfuric acid, but not for the other types of drain openers. If a child spills sulfuric acid while attempting to ingest it, the pain from dermal contact will occur more quickly with sulfuric acid than with alkalis. Thus, it is possible that a sulfuric acid spill may be more likely to interrupt a child's actions and prevent ingestion than would an alkali spill. In that case, one would expect the proportion of exposures that include dermal contact (such as spills) to be similar across the various types of drain openers, and ingestions to be lower for sulfuric acid compared to other types. Instead, the data reflect that when children under five are exposed to a drain opener, they are more likely to spill or otherwise have dermal contact if the product is sulfuric acid than if it is any other type of drain opener, a result for which there is no obvious explanation.

These data may reflect differential coding of exposures rather than true differences in the distribution of dermal versus ingestion exposures. Young children interact with products in many ways that are unrelated to ingestion. Yet ingestion is a natural concern when a child is found with or near a hazardous product, even if there are no signs of either a spill or ingestion. For example, among the in-depth investigations discussed below, of the 17 child incidents coded as poisonings due to ingestion, seven were cases in which the ingestion was suspected, but based on observation and examination, may not have occurred. Based on discussions with an AAPCC staff member, similar events involving children may remain coded as ingestions in the TESS database when there are no obvious effects because ingestion cannot be ruled out (Wm. A. Watson, personal communication, 2-22-05). Because sulfuric acid products act more quickly than alkalis, especially the most common low concentration types, ingestion may be easier to rule out than with alkaline products. Consider, for example, the circumstance in which a child is found with a bottle of sulfuric acid drain opener with some of it on her hands, face, and clothes. No one saw the child drink some of it, but just in case, the caregiver washes the child's mouth as well as the areas of skin contact, and gives her milk to drink. If the child has chemical

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¹⁴ Material Safety Data Sheets contain product and hazard information developed by product manufacturers as required by CFR 29 1919.1200.

burns to the hands and face, but no burns to the comparatively more delicate oral tissues, it is possible that the exposure would be coded as dermal. In a similar exposure with an alkali, the child may be given the same first aid in time to prevent burns because alkali reacts more slowly. Because of the possibility that the child ingested some of the drain opener, the event may be coded as both dermal and ingestion because the lack of oral burns or gastrointestinal effects can be attributed to first aid. Thus, it is possible that alkali exposures among children may be more likely than sulfuric acid exposures to be recorded as ingestion or, in the case of a spill, as both dermal and ingestion, when there is doubt about the latter route. If so, this may be reflected in outcome data as well, by increasing the proportion of alkali exposures resulting in little or no effect. Although these data are interesting, there is insufficient detail to support a particular causal conclusion regarding what differences there may be regarding drain opener exposure route among children under five.

Review of In-Depth Investigations (IDIs)

Overview

The reader is cautioned that the in-depth investigation reports reviewed here are based on incidents from differing sources, such as NEISS reports, CPSC Hotline calls, and Internet complaint reports. Incidents reported to these various sources do not constitute a random sample, nor are the incidents assigned for investigation randomly chosen. This set of reports, therefore, may not be representative of drain opener incidents in general. For example, a disproportionate number of incidents involving children under five may be investigated because of the agency's mission to address injuries among vulnerable populations. Therefore, numbers or percentages presented here are provided only to describe this sample of investigated incidents. They cannot be applied to the incidence of drain opener exposures or injuries nationally, as can NEISS data. IDIs, however, provide background information and scenario details that can be useful in understanding the incidents that occur, and can help characterize the behavioral components of drain opener incidents.

Hazard Analysis (HA) staff provided 106 in-depth investigation reports (IDIs) for team review. Of the total, three involved products other than drain openers, and were excluded from further consideration. HS staff reviewed the documents and categorized the incidents as those involving drain openers containing alkali, hydrochloric acid, sulfuric acid, mixtures of drain openers or drain openers with other products, and drain openers of unknown type. In 88 cases a single product was involved, including 54 identified as alkali, 10 as sulfuric acid, 1 as hydrochloric acid, and 23 as unknown. Combinations of products were reported in 13 IDIs. In three of these neither product was identified. Three reported the mixing of alkaline drain openers and bleach, and one each mixing two different alkaline brands, an alkaline liquid with an alkaline powder, an alkaline product with hydrochloric acid, an alkaline product with sulfuric acid, and an alkaline product with an unknown product. In the two remaining reports, bleach was mixed with sulfuric acid in one, and with an unknown product in another.

The number of incidents described in the reports totaled 101¹⁵, and the number of victims, 103. The reports describe a wide variety of incidents of injury or potential injury due to exposure to drain cleaners involving actual and suspected ingestion (25), ¹⁶ inhalation of fumes (16), eruption from drains or toilets (6), and contact resulting from spills (20), splashes (27) or other events

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¹⁵ One report was limited to a complaint that the cap on the product, an alkaline, was not child-resistant; no incident or injury occurred. In one case more than one incident is reported in the document, and in others, the same incident is reported in more than one document because two people were injured.

¹⁶ Note that the term "ingestion" is used broadly, and includes, for example, incidents in which the amount is believed to be a drop or a few crystals of drain cleaner.

(14).¹⁷ Incidents involving children versus those involving adults are discussed separately below, followed by a summary of the resulting injuries.

Child Incidents

Forty of the incidents involved children. Included were seven children ages six to fifteen, and 33 children under five. Of those, 27 ranged in age from 10 months through two years. Consistent with childhood poisonings in general, the modal age (13 incidents) was two. As is also typical for this age group, the incidents usually occurred during brief routine lapses of direct visual supervision. In some instances products were in their usual storage place, and in a few, children reportedly removed child-resistant closures. In others, products were left out after being used, had been transferred to other containers, or had been emptied and put in a trash can.

In eleven incidents children ingested drain opener from the product container; in three of these, they also spilled the product on themselves. Five children reportedly ingested drain opener or diluted drain opener from something other than the product container, including cups, a clogged sink, and a clogged water fountain. In one of these, the child ingested drain opener from a cup, then spilled it on himself and on an adult as he threw down the cup. Ingestion was suspected, but apparently did not occur, in seven incidents.

Children also were exposed to drain openers in a variety of intentional and unintentional ways that did not involve ingestion. These included children opening containers of liquid or dry drain openers and spilling some of the contents on themselves, mouthing the cap of a drain opener bottle, pouring the remaining drops of a used container into a hand to smell it, and playing with a container found in a dumpster. In one case a container fell in a store and broke, splashing a three-year-old nearby. In a second, similar incident, a 13-year-old dropped a bottle of drain opener as he took it from a store shelf; the cap came off and it spilled in the boy's face. The exposure was indirect in some cases. One child, for example, was splashed when he dropped toys into a floor drain containing drain opener. Another picked up and mouthed a towel that a maintenance worker had used to wipe up drain opener from a burst pipe. In a third case, someone spilled drain opener near toys. Although the spill was cleaned up, some of the drain opener apparently seeped into a toy drum; it later leaked onto a child's stomach as he played with the drum. Two children, in separate incidents, were taken to the emergency room after being sickened by drain opener fumes.

Adult Incidents

Adult victims ranged from 19 to 90 years of age, with all but six aged 65 or younger. The reports describe a wide variety of incidents involving normal and foreseeable use and misuse of the drain openers. Most occurred as splashes or spills either just before or during use (e.g., while opening, walking with, or setting down the container, pouring the drain opener, adding water), or shortly after use (e.g., while using a plunger or removing a trap). Many involved what can be termed performance errors of various types. Typical minor errors that are common in routine manual tasks involved lack of precision and inadequate control of the container, resulting in splashes. For instance, one user explained the incident by saying he probably poured the drain opener "too fast," and another bumped the container against the faucet while pouring. Examples of more serious errors suggesting lack of planning or foresight regarding consequences are those in which consumers removed traps or cut pipes after using drain

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¹⁷ More than one type of contact occurred in some incidents. For example, an eruption caused by a mixture of drain openers resulted in both chemical burns and inhalation injuries.

openers. In some cases nothing was used to contain the resulting spill. Many incidents also involved errors of omission such as failure to use gloves, eye protection, or adequate ventilation, or incorrect use of the product, such as using a drain opener after bleach had been used, or using hot water rather than cold. These may reflect a lack of knowledge in some cases, as well as the limited effect that warnings and instructions have on behavior. A few incidents involved lack of communication between different parties working on the plumbing. In these cases, the exposed person was unaware that a drain opener had been used. As with the in-store incidents involving children, a number of exposures among adults involved new bottles of drain opener, either in stores or during transport from stores. One container was still in a shipping carton, and the cap had come off. Two others spilled because they had loose caps. Three leaked, one after it had been dropped, one because it had a pinhole, and one for an unknown reason.

Injuries

As originally coded, the injury diagnosis was reported as a chemical burn in 63 incidents, as poisoning in 35, as dermatitis/conjunctivitis in 3 cases, and no injury in 2. About a quarter of all the incidents involved the eye, and another quarter affected the face or mouth. Poisoning cases included 16 reports of inhalation as well as actual and suspected ingestions. Few of the incidents had serious consequences, and where reported 18, almost all the victims had fully recovered at the time the investigation was conducted. Summaries of the IDI narratives for incidents in which the victims were admitted and treated and/or required additional treatment are presented below.

- A 63-year-old woman sustained chemical burns to her face and chest when a drain cleaner solution splashed on her after it exploded. She was mixing two brands of unknown type into one container to conserve storage space. She was taken to the hospital, treated, and admitted overnight. (960806HEP9002)
- A 36-year-old male mixed two different drain cleaners (an alkali and an unknown) into the drain and then stuck a wire hanger down it to help remove the clog. The drain erupted and he was splashed on the face and chest with drain cleaner and breathed in a thick, heavy gas emitting from the drain. He was taken to the hospital by ambulance, admitted, and treated for poisoning and chemical burns. He was released three days later. (020320HEP2721)
- A four-year-old was injured at his grandfather's house when he ingested a few sips of sulfuric acid drain cleaner that his grandfather had poured into a cup thinking it was juice. The victim sustained internal and external burns as well as poisoning. He was taken to the hospital, transferred to another hospital, and admitted. He was treated for his injuries and remained in the hospital for two weeks before being released. At the time of the investigation, the child required weekly treatment. (011015HEP5281)
- An 18-month-old girl ingested crystals from an open bottle of (alkaline) drain cleaner while visiting her grandparents' house. She was taken to the hospital, admitted, and treated for poisoning. The victim spent five days in the hospital. (990608HEP9007)
- A 52-year-old man was injured while working maintenance at a resort hotel. He put crystal (alkaline) drain cleaner in a drain when it suddenly erupted and splashed into both eyes. He was taken to the hospital and then transferred to another hospital, where he was admitted and underwent surgery. He was released a couple days later, and continued treatment at the time of the investigation. (020930HEP0601)

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¹⁸ Many of the IDIs are based on a survey format that specifically questions whether first aid was given and whether the victim was fully recovered at the time of the investigation. Others do not include these questions, and the information may or may not be given in the report.

A 28-year-old man sustained chemical burns to his eyes when the sulfuric acid-based drain cleaner he was pouring into his bathroom sink splashed up and into his eyes. He was taken to the hospital, treated, and released with a referral to a doctor. He was unable to work for a week (960430HEP9009).

In seven instances the report narrative indicates that there was no apparent injury. Five of these involved children who it was thought might have ingested drain cleaner (four alkalis and one hydrochloric acid). One involved an unknown type of drain cleaner that splashed the hands and mouth of a 90-year-old woman. She washed her hands and rinsed her mouth, then sought treatment in case she had swallowed some of the cleaner. The final case involved a newly purchased bottle of sulfuric acid drain cleaner which spilled on a woman's hand as she lifted it by its cap. She rinsed her hand immediately, and then her companion poured baking soda on it.

Discussion

The "Kleenex Syndrome"

The petitioner relates this concept to his discussion of staff's conclusion in the 1996 briefing package that sulfuric acid drain openers and alkaline drain openers pose similar risks. Sixtythree percent of the incidents identified in this earlier review of NEISS data were reported as alkaline drain openers and six percent were reported as sulfuric acid drain openers (Kissinger, 1996). 19 The petitioner believes that the number of incidents involving alkalis was overestimated, and attributes this to a phenomenon to which he refers as "The Kleenex Syndrome." The brand name "Kleenex" has become a generic noun commonly used to refer to tissues of any brand. The petitioner asserts that the same is true of the alkaline brand "Liquid Plumber" (sic), and that both consumers and emergency medical providers frequently use that name to refer to any drain cleaner when filing incident reports. He contends that many incidents with sulfuric acid drain openers are mistakenly categorized as alkali-related because of this error, thus inflating both the proportion and severity of incidents involving alkalis, and creating the spurious result that the two types are equally hazardous.

EC staff estimates that sulfuric acid drain opener products account for 3 percent to 5 percent of unit sales of drain openers to consumers, and perhaps up to 10 percent of consumer applications because smaller amounts per treatment are required than with alkalis (Franklin, 2005). The estimated percentage of NEISS incidents attributed to sulfuric acid products reported in the 1996 briefing package (about 8 percent of known types), is similar to that in the current data (Kissinger, 1996)²⁰. As a proportion of the known drain openers in each of the data sources, they account for 10 percent of the estimated number of drain opener incidents reported through NEISS from 1995 through 2003 (Table 2, Ingle, 2005); 6 percent of drain opener exposures among children under five reported through TESS from 2000 through 2002 (Table 6, Ingle, 2005); and 10 percent of drain opener exposures for all age groups reported through TESS for 2001 through 2003 (Table 14, Ingle, 2005).

It is likely that there is an element of error in the incident records, regardless of source. Recall is often particularly poor under conditions of stress, and delays between the time of the incident and the time of the report may degrade the accuracy of the details reported. Familiar "top of the mind" brand names are more likely to be remembered than uncommon names, thus reporting

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¹⁹ The smaller percentage of cases coded as alkalines (32%) in staff's current analysis of NEISS data can be attributed to close review of cases by HS staff. Incidents in which the type of product could not be confirmed based on details of the report were coded as unknown.

The 1996 analysis did not include TESS data.

may be biased toward those brands. To busy emergency room staff it may seem more important to record that a patient was exposed to a drain opener than to be accurate as to the brand or type. Despite these factors, the available data provide little support for the petitioner's specific claim.

The proportion of incidents involving sulfuric acid drain openers reported in the TESS data is similar to that in the NEISS estimates reported by HA staff both in 1996 and currently, and with EC staff estimates. It seems likely that TESS reports are relatively reliable regarding the general type of product involved in drain opener exposures because of the nature of the reports and the proximity in time between the incident and the report. TESS records are based on phone calls to Poison Control Centers staffed by Certified Specialists in Poison Information.²¹ According to the most current AAPCC Annual Report, 92.7 percent of exposures reported through TESS occur in a residence, and more than 75 percent of reported calls are made from a residence (Watson et al., 2003). The container is likely to be on hand in the home setting, and poison control center staff routinely ask for the exact product name and active ingredient from the product label. This information is then searched in POISINDEX®, a database containing the ingredients and treatment protocols for a wide variety of products. Even under these conditions, with trained staff whose purpose is to help track and address exposures to hazardous substances, some level of error is expected. However, given the high proportion of incidents that occur in and are reported from a residence, it seems unlikely that large numbers of sulfuric acid drain opener incidents would be mistakenly coded as exposures to "Liquid Plumber." 22

The investigated incidents do not support the petitioner's claim. A brand name was reported in 67 of the 101 incidents. Of those, the alkaline product the petitioner identifies as the "Kleenex" of drain cleaners was reported in only nine cases. Another leading alkaline brand was named in 34 reports. The latter includes the granular ("crystal") form in six incidents, which is unlikely to be confused with sulfuric acid. It is possible that the liquid forms of this brand product could be incorrectly named in some acid-related incidents. However, even with the two liquids combined, familiar brand name products account for only 36 percent of this sample.

It seems more likely that incidents involving sulfuric acid may be categorized as "unknown drain opener," rather than misclassified as incidents involving alkalis. Acid drain openers are not widely available in the same stores as popular brand name alkaline products with low hydroxide concentrations, and reportedly are more effective. It seems likely that many consumers who seek out a product at a specialty store do so because the more familiar products have not been effective in resolving their plumbing problems. If they do not have the container (e.g., at the emergency room), consumers may not recall the names of these less familiar acid products, however, many are probably aware that what they have purchased is not the same as the brand name drain openers in grocery stores. Anecdotally, the packaging and labeling of the two classes of products (i.e., low concentration alkalis in grocery stores and high concentration acids in hardware stores) is dissimilar, which would reinforce the perception that the two types are different, and may lessen the likelihood that an acid product is reported as a popular brand name alkali.

The foregoing may not hold for higher concentration alkaline drain openers. Like sulfuric acid, these products are sold in hardware stores. Staff has not done a thorough review and

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²¹ http://www.poison.org/

The same may not be true within product brands. POISINDEX® may list a number of products that have the same brand name, but with different concentrations or formulations. Although there has been no systematic study of the question, it is possible that Poison Control Center Staff enter the first name on the list, thus biasing the frequency of that specific product within a line of brand name products (S. Barone, personal communication, January 2005).

comparison of the packaging and labeling of the different types of drain openers. However, some sulfuric acid and higher concentration alkaline products are available in one-quart packages that are superficially similar, and at least one firm makes both types with the same brand name. Incorrect identifications seem more likely between these two types. These higher concentration alkaline products are more likely to result in serious injury than are their low-concentration counterparts (Brundage, 2005). However, with the exception of products that also have familiar brand names, it is not clear that reports are likely to be biased toward either sulfuric acid or high concentration alkaline drain openers.

Consumer Response to Drain Opener Exposures

The second issue raised by the petitioner concerns consumers' knowledge and ability to respond when an exposure to sulfuric acid drain opener occurs. He states that because consumers do not have the type of knowledge and training that professional users of sulfuric acid have, they are helpless to respond. As evidence, Dr. Fox presents an incident in which a young boy was severely injured when a bottle of sulfuric acid spilled on him. As described in the petition, "...not even the paramedics and police knew how to respond to this boys (sic) SADO burns. They were dribbling saline solution on him when they should have been washing him with a garden hose full force. Another member of the family who also got sulfuric acid on her skin was not even washed until she got to the hospital emergency room. Instead of washing her with copious amounts of water, the police were questioning her..." Very little information is provided about the incident, however, what is presented leaves the impression that no attempt to wash off the acid from either victim was made between the time of the spill and the arrival of emergency personnel. No explanation is given as to why the attending medical personnel responded as they did.

Among the available sources of data, only the IDIs provide information relevant to this issue. Where information on first aid was included in the report, 77 of 86 respondents reported that first aid was given. Typically the victim's skin, eyes, or mouth (as appropriate) were "flushed," "rinsed," or "washed," with water. Those reporting effects of fumes (i.e., inhalation) left the area, and sometimes flushed their eyes as well. People often do react in inappropriate ways to emergencies, for example, due to panic, lack of knowledge, or shock. However, the apparent lack of action prior to the arrival of emergency personnel in the incident described in the petition may be atypical. Although there are exceptions, the usual response to pain is to try to interrupt or diminish the stimulus causing the pain, as when we pull a hand away from a hot surface, or cover our ears to muffle a painfully loud noise. Sulfuric acid reportedly produces a burning sensation within seconds (Brundage, 2005, citing Davidson, 1927); a normal response to alleviate the pain is to do something to remove the acid. While most consumers may have little or no specific knowledge of chemicals, most are likely to have had some experience with at least minor burns, and to have learned that water, especially cold water, helps to relieve the effect. HF staff acknowledges that consumers' response may be inadequate, particularly in extreme circumstances such as that described in the petition. However, the available data suggest that many consumers are more capable than the petitioner assumes, and it is reasonably likely that their responses will be at least somewhat effective.

Labeling Issues

Hazardous household substances are required to bear cautionary labeling under the FHSA. Hazardous substances containing 10 percent or more free or unneutralized sulfuric acid are specifically required to bear the word "POISON" [16 CFR §1500.129(b)]. Additionally, they are subject to Section 2(p)(1) of the FHSA, which includes instructions for handling, use, and first aid labeling. These requirements are generally included in the voluntary labeling standard that

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was developed in conjunction with CPSC staff by the Association of Chemical Producers, Inc., a now disbanded organization. HF staff has not thoroughly reviewed the labeling and packaging of the available brands. Among those seen in local stores, all appeared to include the information required by the FHSA. Some did not meet all provisions of the voluntary standard, such as the requirement for a warning hangtag. At least one brand exceeded the requirements. It was packaged in a clear bag with prominent pictogram warnings and text in two languages.

HF and HS staffs' review of the product labeling for some sulfuric acid drain openers identified one component of the first aid labeling that appears to require updating. The label content regarding how to treat someone who has ingested the product conflicts with current medical recommendations. HS staff (Brundage, 2005) cites sources that recommend giving a child no more than 4 ounces of water or milk, and an adult, no more than 8 ounces, to minimize the risk of emesis. In contrast, the container labels reviewed advise the intake of large quantities of water or milk followed by milk of magnesia, beaten eggs, or vegetable oil.

The petitioner makes the following statement regarding the effectiveness of labeling on sulfuric acid products:

"It is not possible to label a SADO so as to properly instruct and warn the ordinary consumer about the dangers it presents. Once a consumer gets splashed with SADO he or she must know what to do immediately...the label has to *guarantee* that the consumer will read and understand the label before they use the product and follow all safety instructions to the letter. To my knowledge, there is no such label."

No label can guarantee that users will read, understand, and follow product warnings and instructions accurately and consistently. However, the petitioner's tone suggests that if the label cannot *guarantee* full knowledge and 100 percent compliance, the consequences of a sulfuric acid exposure are necessarily dire. The available data suggest that is not the case. In the ten investigated incidents involving sulfuric acid, the details reported indicate that it is almost certain those involved failed to comply with one or more of the warnings or instructions on the container. Yet only one case, involving ingestion, approaches the severity of the incident the petitioner reports, and some appropriate action was reported in all. The number of incidents here, however, is small, and may not be representative. The TESS database does not provide scenario details, and like the in-depth incident reports, may not be representative of sulfuric acid exposures in general. However, it includes a large number of reported exposure events for which some information is available. Among the sulfuric acid drain opener exposures, the large percentage that were confirmed or judged to have resulted in little or no effect [73 percent among children under five (Table 7²³) and 66 percent among all ages where outcome was known (Table 5²⁴)] suggests that the petitioner's claim is overstated.

Sulfuric acid products are inherently hazardous, and their safe use poses certain challenges that seem likely to limit the effect of warning labels on consumer behavior. For example, according to the package labels on two brands of sulfuric acid drain opener, proper use requires

²⁴ The percentage given here is the sum of the percentages of exposures in the None and Minor outcome categories, where outcome was known, for all ages shown in Table 5 of this memo. See Table 15, Ingle, 2005, for the counts of exposures to sulfuric acid drain openers on which these percentages are based.

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²³ The percentage given here is the sum of the percentages of exposures in four outcome categories for children under five shown in Table 7 of this memo: 1) confirmed None; 2) confirmed Minor; 3) not followed because the effect was judged as likely to be nontoxic; and 4) not followed because the effect was judged as likely to be minimal. See Table 9, Ingle, 2005, for the counts of exposures to sulfuric acid drain openers on which these percentages are based.

protective glasses and gloves. ²⁵ This is a relatively high "compliance cost" if the consumer does not have these items; it entails both the inconvenience of obtaining them, and further delay in resolving the plumbing problem. The cost of compliance—what it will cost the user in terms of time, effort, inconvenience, and so on, to comply—is a powerful factor influencing the likelihood that users will obey warnings. Even small increases in cost can dramatically reduce compliance (cf. review, DeJoy, 1999). In research studies using a chemistry lab paradigm, Wogalter and his colleagues (1989) found compliance among students was high if protective equipment was at hand, but very few students used it if they had to obtain it from the next room. In a more realistic home setting, among subjects testing an "industrial strength" cleaning product, few used the recommended mask and gloves except when these items were supplied in the package (Dingus, Wreggit & Hathaway, 1993). These and similar studies suggest that consumers are unlikely to use protective equipment unless it is provided.

A second issue that raises questions regarding the effectiveness of warnings is the possibility that hot acid will erupt²⁶ from the drain as it reacts with clog material and water, or other chemicals that may have been used. It is not clear how frequently, under what conditions, or how quickly, this may occur. The possibility, however, can lead to odd contradictions and potential conflicts in the instructions and warnings. For example, the instructions for one product call for slowly pouring the acid while keeping hands and face away from the drain opening. After pouring, one is to place an inverted bucket or dishpan over the drain immediately. Slowly or carefully pouring the needed amount²⁷ of drain opener takes some minimum amount of time; if an eruption occurs concurrently, a user would not be able to react quickly enough to avoid it. Conversely, if there is no eruption when the consumer does take the trouble to quickly place a container over the drain, the warning becomes a false alarm that may be ignored during future use. Similar to the familiar "cry wolf" phenomenon, when consumers' experience with a product contradicts the information presented in a warning, the warning is perceived as less credible, and compliance is less likely.

A third issue that may affect compliance is the appropriate first aid response to dermal contact. General guidance for external contact typically states to flush, wash, or rinse with water for at least 15 minutes. It is not at all obvious why a long period of flushing is required, and, consumers—assuming they have read the warning—are likely to perceive it as excessive. Compliance is likely to be low when warnings seem to the user to lack credibility; most will rely on physical cues, rinsing only until it looks and feels as if the acid is gone. This is likely to be well short of the recommended 15 minutes, and if insufficient, injuries may be more serious as a result.

Appropriate first aid also raises some practical concerns that, at least in some circumstances, may limit effective compliance with the label instructions. Sulfuric acid is particularly damaging to vulnerable eye tissues, and immediate first aid is critical to the outcome (Brundage, 2005). The correct first aid is to hold the eye open and gently flush it with running water for at least 15 minutes. In a setting where an eye wash station is nearby, there is a reasonable likelihood of effectively rinsing the eye. For an injured consumer at home, this procedure may be quite difficult to perform, especially if both eyes are involved. For example, the space between the faucet and the sink, the dimensions of the head, and the position of the eyes may make it

²⁶ Based on the incident investigations, eruption may also occur with alkaline products under some conditions

²⁸ Based on HS staff's review (Brundage, 2005), this is true of alkaline drain openers as well.

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²⁵ Material Safety Data Sheets, which contain product and hazard information developed by product manufacturers, also include use of a face shield and protective clothing.

²⁷ Product instructions vary, but examples include 4 to 8 ounces for small drains or toilets, 32 ounces for floor drains, and a gallon for septic tanks.

impossible to flush them properly. A shower is likely to be the most effective option, however, if that is also the site of the clogged drain—which now contains acid—there are potential limitations to flushing the eyes, as well as to effectively rinsing off larger or multiple body surfaces.

In contrast to these limitations are factors that tend to promote warning effectiveness. A consistent finding in the research literature is that how hazardous a product is perceived to be influences how likely people are to read and comply with warnings (cf. review, DeJoy, 1999). It seems likely that there is some level of knowledge among the consumers that acids can cause severe burns, even among those that have no specific knowledge of chemicals. For example, acid injuries, and the intentional use of acid as a weapon, are a theme that recurs in popular entertainment media such as comic books, movies, and television series. Thus, consumers may have a baseline perception that sulfuric acid drain opener is hazardous. A second factor is familiarity. Products that are used routinely are familiar, and consumers tend to be more comfortable with them, while unfamiliar products tend to be perceived as more hazardous. Sulfuric acid drain openers constitute a small portion of the consumer market, suggesting that many consumers do not use them regularly, and may be inclined to look for and heed warnings and comply with instructions.

Although the limitations discussed above cannot be resolved directly through labeling and instructions, they do suggest areas in which the current labeling might be modified to help promote compliance. For example, some of the products reviewed have separate lists of instructions and warnings. Although separate warnings can be useful, and may be appropriate, research suggests that consumers may be more likely to read and comply with warning statements that are incorporated into the use instructions (e.g., Friedmann, 1988; Frantz, 1992; Frantz, 1994; Edworthy et al., 2004). In this instance, when correct use of the product calls for unusual steps, such as finding a container to cover the drain in advance, incorporation seems warranted. Another example concerns the use of safety goggles and gloves, which would help prevent serious eye and skin injuries that can result from unexpected eruptions and splashes. The warning to use them was not displayed conspicuously on the labels reviewed. On one package, this precaution is embedded in a lengthy string of warnings presented in paragraph form that requires one to read relatively small print around the curved surface of the bottle. Information presented in this format is less likely to be read or remembered than other styles, such as list of bullet items (DeSaulniers, 1987). More importantly, it is unlikely to be noticed at the point of purchase, when the consumer could obtain protective equipment if needed. The most effective approach, however, would be to provide this equipment. Dingus and colleagues, in the study cited previously, found that when gloves and masks were provided in the package with an "industrial strength tile descaler," subjects perceived the product as more hazardous. Eighty percent of subjects used the gloves and 50 percent used the masks, even when there was no warning message advising them to do so (Dingus et al., 1993). The addition of warnings enhanced compliance.

Possible Effects of Implementing the Petitioner's Recommendations

The effects of implementing the petitioner's recommendations are uncertain at present. The first option proposed is a ban for consumer use. Note that in four of the investigated incidents, the product used in the home had been obtained where the victim worked (sulfuric acid in two cases, a crystal alkali in one, and an unknown drain opener in one), and a number of incidents occurred following use of drain openers by plumbers or maintenance staff. These incidents

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²⁹ Some examples include the 1944 film *Dead Man's Eyes*, comic book/strip episodes of *Dick Tracy* and *Superman*, and the *Batman* character "Two-Face."

suggest that although a ban for consumer use might reduce exposures to sulfuric acid, it may not prevent all such incidents.

A possibility that was raised in the 1996 briefing package is that substitutions may lower injuries due to sulfuric acid, but result in increased frequency of injuries with other types of drain openers (Barone, 1996). As stated previously, it seems likely that most consumers who seek out a sulfuric acid product do so because they perceive it to be more effective for their needs than commonly available commercial brands, and it is considerably less expensive than is a plumber. As discussed by EC staff (Franklin, 2005), effective mechanical substitutes such as snakes or augers may not be a viable option for many consumers. Though inexpensive, they require more strength, skill, and time than chemicals, and can be messy to use as well. If sulfuric acid products were to become difficult to obtain, it is reasonable to presume that many consumers would turn to other chemical drain openers that are stronger than common grocery store brands, such as high concentration hydroxide products. HS staff concluded that both alkalis and sulfuric acids pose the risk of severe injury, however, it is not clear that one can make direct comparisons between the injury potential of, for example, a 93 percent sulfuric acid drain opener and a 40 percent hydroxide drain opener. The lack of sensory response, at least to dermal contact, is of concern with hydroxides. Exposure to sulfuric acid is likely to trigger an emergency response. If hydroxide spilled or splashed on the skin has no obvious effect, consumers may delay washing, and suffer more serious burns as a result.

The staff has made no assessment of the relative hazardousness or effectiveness of sulfuric acid at 84 percent concentration versus the higher concentrations currently available. According to patent information (Vlahakis, 1978) provided by the petitioner, drain openers with a sulfuric acid concentration of about 80 percent to 84 percent produce less heat, allowing a "time-based safety factor" of two minutes before severe burns may occur, and are effective at breaking down clogs consisting of a sanitary napkin. Prohibiting concentrations higher than 84 percent, however, may preclude the use of other potentially effective methods of risk reduction. For example, one firm markets a 94 percent sulfuric acid product it describes as a "buffered organic digester" which "gradually heats up." The firm claims the product is effective on clogs, but is "...so safe that...you have five minutes to safely wash it off." It is unknown how either of these products would be perceived on the skin; however, buffering or reducing the concentration may not cause a significant delay in sensory response, as occurs with hydroxides. In the study cited by HS staff (Davidson, 1927), response latency to a 50 percent solution of sulfuric acid was 45 to 50 seconds. In any case, despite the possibility that varying the concentration or other formulation characteristics of sulfuric acid products could provide a safety factor, prompt washing would still be required to reduce the risk of serious injury following exposure (Brundage, 2005).

In conjunction with a concentration restricted to 84 percent, the petitioner requests that sulfuric acid drain openers be restricted to "one-shot" containers of unspecified amount. EC staff states that sulfuric acid drain openers currently are available in pint, quart, half-gallon, and gallon containers, with the quart size being the most common (Franklin, 2005). According to package directions for one brand, the amount required varies depending on use, with "4 - 8 oz" specified for toilets, "one cup" for "small drains," and one gallon for 250-gallon cesspools and 500-gallon septic tanks. The container also states, "Repeat as needed." A second brand specifies 4 ounces for "small drains" and 32 ounces for "floor drains," as well as a gallon for cesspools and septic tanks, but does not refer to repeat treatments. It seems impractical to limit consumers to small four to eight ounce containers when they may need as much as a gallon. Size restrictions may lower the amount of product available to be spilled; however, if a container is spilled as in

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³⁰ http://www.plumbest.com/floweasy/index.html

the incident reported by the petitioner, even 4 or 8 ounces is likely to be sufficient to cause extensive tissue damage (Brundage, 2005).

Among the incidents reported in the IDIs, it seems unlikely that many might have been prevented by a restriction on container size. In this sample, 74 of the 101 incidents occurred while a drain opener was about to be used (e.g., opening a bottle, tripping while carrying an open container), was in use (e.g., pouring, eruption, plunging, mixture with previously used products), or had recently been used (e.g., spills from removed traps, ingestion of residue from a used product container, cup or clogged sink). In one of these incidents, the report is explicit that a user with arthritis was splashed because she had difficulty handling a container of unknown size. Although it is not included in other reports, it is possible that among the several incidents that involved users who were splashed while pouring some type of drain cleaner, that the size and/or weight of the product was a factor. If so, it may be that smaller packages, being easier to handle, could lessen the likelihood of incidents of this type. On a related point, several team members have noted that the tall narrow quart bottles (approximately 10.50 in. tall and 3.38 in. diameter) typically used for sulfuric acid drain openers are likely to be easily tipped over. Interestingly, only two of the 101 incidents involved a bottle of drain opener that was knocked over.31 In one of these, the product was in use, and in the other, it was knocked over as the user reached for something else on a shelf. Unfortunately, no details of the containers were given in the reports. It is not known if such incidents occur infrequently, or if they are simply underrepresented because the in-depth investigations as a group do not accurately reflect the distribution of types of drain opener incidents. However, it seems possible that small "one-shot" containers would reduce the likelihood of some incidents of this type, for example, by reducing the likelihood that partially used containers will be stored. If they were also made with a wide base, the potential for tipovers might also be reduced.

There may be potential trade-offs in limiting the quantity per container to the lowest "one-shot" use amount. This may require consumers to use more than one container for various applications. Instead of purchasing one container, several may be purchased and stored. This may increase the number of containers to which children are exposed. Smaller, lighter packages may be easier for children to handle, and may be more appealing, for example, if they appear more similar to drink containers than the larger packages currently used. The childresistance of the closures, however, may be unaffected by the size of the container.

Summary

The information reviewed for this report does not support the petitioner's claim that the number and severity of injuries involving alkaline drain openers reported in the incident data are inflated due to what the petitioner terms the "Kleenex Syndrome." Exposure data in the TESS database do suggest that incidents involving sulfuric acid drain openers may result in more serious effects than do those involving alkaline drain openers. However, the comparison is between sulfuric acid drain openers with concentrations of 84 to 94 percent and hydroxide drain openers with concentrations ranging from less than 2 percent to 40 percent for liquids, and near 100 percent for solid forms. Thus, the results may reflect the widespread availability and use of very low hydroxide concentration alkaline products, which are expected to be less hazardous than concentrated sulfuric acid products. This may mask the injury potential of high concentration hydroxide products available for consumer use. Additionally, although the TESS database is

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³¹ Note that this low frequency cannot be interpreted because of the nature of the investigations as a dataset. For example, it is possible that incidents of this type occur much more frequently, but were not chosen for investigation.

large, it reflects only exposures reported to poison control centers that submit data to the AAPCC, and thus may not be representative of drain opener exposures in general.

The details on incidents involving drain openers are quite limited. The information available from in-depth investigations does not support the petitioner's assertion that consumers are helpless to respond when exposed to sulfuric acid drain openers. Normal human response to pain or discomfort is to act to stop it or minimize it, and on the whole, victims received some appropriate first aid regardless of the type of drain opener involved.

The requirements for safe use of these products, and adequate response to exposure, are likely to limit the effectiveness of warning labels and instructions to address the risks they pose. Conversely, certain factors affecting sulfuric acid may increase the likelihood that consumers will look for and comply with the warnings and use instructions. Optimization of these materials, particularly regarding the use of protective equipment, may help promote user compliance, and thereby reduce the risk of injury. Additionally, based on HS staff's review, the first aid instructions for ingestion given on the labels of at least some sulfuric acid drain openers are inconsistent with current medical recommendations.

The impact of implementing the petitioner's request is unclear. HS staff advises that, depending on several factors, including concentration, both alkaline and sulfuric acid drain openers can cause severe injuries. Thus, one possible effect of removing sulfuric acid drain openers from the consumer market may be an increase in injuries due to high concentration hydroxide products. The petitioner's alternative is to limit sulfuric acid drain openers to concentrations of 84 percent, and to an unspecified "one-shot" size. Restricting the sale of sulfuric acid drain openers to small (e.g., 4- to 8-ounce) containers may help reduce the likelihood of some types of incidents. It seems likely, however, that most incidents occur while the product is in use, and container size may have little impact on the likelihood of injuries. Further, in an exposure/treatment scenario such as that described by the petitioner, even small volumes of sulfuric acid could cause severe injury.

Staff has made no assessment of the hazardousness or effectiveness of sulfuric acid drain openers at lower concentrations. A patent provided by the petitioner asserts that this concentration produces a lower level of heat resulting in a two-minute safety factor before severe burns may occur. This may help reduce the likelihood and severity of injuries with sulfuric acid drain openers; however, it may be overly restrictive. An even longer "safety factor" is claimed by the manufacturer of a 94 percent sulfuric acid drain opener. Changes such as these may reduce the hazardousness of sulfuric acid products. Prompt washing would still be required to prevent or minimize the potential for serious injury following exposure.

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TAB E

United States Consumer Product Safety Commission Washington, DC 20207

Memorandum

Date:

26 July 2005

TO

Kristina M. Hatlelid, Project Manager Sulfuric Acid Drain Opener Petition

Directorate for Health Sciences

THROUGH:

Gregory Rodgers, Associate Executive Director GB

Directorate for Economic Analysis

FROM

Robert Franklin #F

Economist

Directorate for Economic Analysis

SUBJECT :

Petition to Ban Sulfuric Acid Drain Openers: Market Information and

Economic Considerations

Background

The Commission received and docketed a petition (Petition HP 04-02) requesting that the Commission ban sulfuric acid drain openers for use by consumers. The petitioner asserts that sulfuric acid drain openers (SADOs) are substantially more hazardous than alkaline drain openers and are too hazardous for use by ordinary consumers. If the Commission does not ban SADOs, the petitioner urges the Commission to limit the amount of SADO in containers intended for consumer use to just the amount that would be required for one use and to limit the maximum sulfuric acid concentration of SADOs intended for consumer use to no more than 84 percent.

This report provides information on the market for SADOs, their substitutes, and the societal cost of injuries associated with chemical drain openers. It also discusses some of the potential economic implications of a ban of SADOs. The discussion is based on information that was readily available, including that provided by the petitioner, SADO manufacturers, public comments, information developed by CPSC staff during previous work on SADOs, and information from trade and other publications.

Product Description

SADOs are a chemical method for removing clogs in wastewater drain pipes. The sulfuric acid reacts with the water in the drain and produces heat. The heat softens and melts some components of clogs, such as grease. According to SADO manufacturers, the sulfuric acid will also dissolve or breakdown hair and cellulosic materials (e.g., paper).

The sulfuric acid concentrations of SADOs range from approximately 84 percent to 94 percent. The balance of the formula can include ingredients such as coloring agents and inhibitors that prevent the acid from damaging metal pipes. The SADOs with the lower acid concentrations are said to produce less heat than the ones with higher acid concentrations. The reduced heat may reduce the risk of injury from the drain cleaner erupting out of the drain.

According to label instructions, most SADO manufacturers recommend 4 to 8 ounces of their product be used per application for most household drains. Thus, each quart bottle contains enough product for 4 to 8 applications. However, a second application is often necessary to remove a clog. SADOs are available in pint, quart, half gallon, and gallon containers, with quarts being the most common size. Sulfuric acid drain openers are widely available in hardware stores; they are much less common in other types of retail stores including grocery, drug, and department stores.

Substitutes

Alkaline Drain Openers

Alkaline drain openers (ALKDOs) contain sodium or potassium hydroxide. Liquid ALKDOs have hydroxide concentrations ranging from less than 2 percent to about 40 percent. Dry or "crystal" ALKDOs can have hydroxide concentrations of between 60 to 100 percent. ALKDOs also produce heat when mixed with the water in a drain pipe. The heat may soften some components of clogs, which may serve to dislodge the clog. The hydroxide will also react with fats, such as grease, to form a soap, which is water soluble. Hydroxide-based drain openers are effective on clogs composed of hair. However, according to SADO manufacturers ALKDOs are not effective on clogs composed of cellulosic materials.

ALKDOs are more widely available than SADOs. Unlike SADOs, ALKDOs (including "gel" and "foaming" formulations) are commonly available in grocery, drug, and convenience stores. Like SADOs, they are also available in hardware stores. However, ALKDOs available in grocery, drug, and convenience stores are generally the liquid ALKDOs with the lower hydroxide concentrations and the dry ALKDOs. The liquid ALKDOs with the higher hydroxide concentrations (e.g., 10 percent or greater) are more likely to be found in hardware or home center stores.³

Of the ALKDOs, the closest substitutes for SADOs are the ones with the higher hydroxide concentrations. It is likely that many people who choose to purchase SADOs do so because they want a product that they perceive as being stronger than the typical ALKDO sold in grocery, drug, and convenience stores, and are willing to make the effort to go to a hardware store to get them. Therefore, if SADOs were no longer available, these consumers might be more

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¹ The recommended dose increases with the diameter of the drain pipe. Four to 8 ounces is a frequently recommended dose for pipes that are 2 inches in diameter or less.

² "Dealing with your Drain," Consumer Reports, January 1994, published by Consumers Union.

³ Hydroxide concentrations are based on publicly available information such as Material Safety Data Sheets.

likely to buy the ALKDOs with the higher hydroxide concentrations that are also available at hardware stores rather than the ALKDOs with the lower hydroxide concentrations.

Hydrochloric Acid Drain Openers

Hydrochloric acid drain openers are available substitutes for sulfuric acid drain openers. Although there appear to be fewer manufacturers that sell hydrochloric acid drain openers for retail sale, based on the reported sales of one brand of drain opener that contains hydrochloric acid, the retail market share of hydrochloric acid drain openers could be similar to that of sulfuric acid drain openers. The concentrations of hydrochloric acid drain openers are usually between 5 and 30 percent.

Hydrochloric acid, like sulfuric acid, can cause significant injuries.⁵ However, hydrochloric acid is a less vigorous acid and causes less desiccation and heat release than sulfuric acid.⁶ The extent to which this reduces the hazards associated with hydrochloric acid drain openers as compared to SADOs has not been determined.

Enzymatic or Biological Drain Cleaners

Enzymatic or biological drain cleaners are available in hardware stores and increasingly in grocery and drug stores. These use bacterial cultures that produce enzymes that digest organic matter, such as grease and soap scum, that coats the inside of drain pipes and that can eventually lead to clogs. Biological drain cleaners will not digest hair directly, but may digest other materials (e.g., grease or soap scum) that hold hair inside the pipes. Biological drain cleaners work on pipes that are slow draining, but are not completely clogged. Therefore they may not be good substitutes for either SADOS or ALKDOs, which can open completely clogged drains. Biological drain cleaners usually require 2 to 5 treatments to get the bacterial colony established. After the colony is established, most manufacturers suggest a maintenance treatment at least once a month to replace bacteria that are washed down the drain or are killed by cleaning solutions, bleach, disinfectants, and so on.

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⁴ Based on the reported sales for the 52-week period ended 10 August 2003 by Information Resources Incorporated, Chicago, Illinois.

⁵ Patricia M. Brundage, CPSC Memorandum to Kristina Hatlelid, "Health Hazards Associated with Sulfuric Acid Drain Openers," (2005).

⁶ Patricia M. Brundage, CPSC Memorandum to Kristina Hatlelid, "Health Hazards Associated with Sulfuric Acid Drain Openers," (2005).

Mechanical Methods

There are several mechanical methods of unclogging drains that are available to consumers, including plungers and snakes or augers. Plungers work by forcing air or water towards a clog and then pulling the air or water away from the clog. The alternating pushes and pulls can break up and dislodge a clog. Plumber's snakes or augers are effective at breaking up clogs and may even be able to pull some objects, such as hair, out of the drain. Retail prices for plungers start at under \$4. Augers can be purchased for as little as \$8.

The primary disadvantages of mechanical devices are that they require higher degrees of skill and physical strength on the part of the consumer than do chemical products. Mechanical methods also may require the consumer to remove things such as cross bars, strainers, mechanical drain plugs, and lift bars from the drain before the device can be used. Therefore, the time it takes the consumer to use a mechanical device may be substantially greater than that needed to use a chemical drain cleaner. For consumers who have the skill, time, and strength, these methods may be effective alternatives to a sulfuric acid or other chemical drain cleaners. For other consumers, they may not represent viable alternatives.

Professional Plumbing Services

Professional plumbing services are the most costly substitute for SADOs. Most professional plumbers use a powered drain auger and can remove pipes and fixtures if necessary to remove a clog. The cost to consumers of using a professional to unclog a drain typically exceeds \$100 for even a simple clog. The cost increases if additional work is involved, such as disassembling pipes or removing a toilet. Because of the high cost of professional plumbing services, many consumers probably try other methods first, such as a chemical drain opener or one of the mechanical devices.

Market for Drain Openers

A 1978 study of the market for chemical drain openers estimated that there were approximately 55 million alkaline and sulfuric acid drain openers sold in 1978, or about 0.7 units for each occupied housing unit. If it is assumed that sales of chemical drain openers are a function of the number of occupied housing units, applying that same ratio to the number of occupied housing units in 2003 suggests that almost 74 million units of chemical drain openers were sold in 2003. This estimate is in line with other estimates of chemical drain opener sales. Based on sales estimates for the year 2000, an estimated 56 million drain openers of all types

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⁷ Final Report on Product/Industry Profile and Economic/Environmental Impact Analysis of Proposed Ban on Sulfuric Acid Drain Cleaners to Deputy Associate Executive Directorate for Economic Analysis, U.S. Consumer Product Safety Commission, by EW Helper, NK Napier, RE Leverenz, PR Beck, and WE Riddle of Battelle, Columbus Division, Columbus, Ohio (31 May 1979). Estimate of unit sales determined by dividing dollar sales by the average retail prices for ALKDOs and SADOs given in the report. Estimate of occupied housing units is from the U.S. Bureau of the Census.

were sold in food, drug, and department stores. However, this estimate does not include sales at hardware, home center, and convenience stores.⁸

A group of sulfuric acid drain opener manufacturers provided CPSC staff with some information on their sales of SADOs for the period 1995 through 2003. According to an industry representative, these manufacturers are the primary manufacturers that produce SADOs for the retail market and most of their sales (93 to 95 percent) were to the retail market. Based on this information and estimates of the total retail chemical drain opener market, sulfuric acid drain openers probably account for about 3 to 5 percent of units (or packages) of drain openers sold to retail consumers.

According to package directions, a typical quart of sulfuric acid drain opener contains enough product for 4 to 8 applications. 10 The typical liquid alkaline drain opener contains only enough product for 1 to 2 applications per quart. Therefore, consumers may be able to get 4 times as many applications from a SADO as from most ALKDOs. However, the liquid ALKDOs with higher hydroxide concentration can contain enough product for 4 to 8 applications, and the dry or crystal alkaline drain openers may contain enough product for 10 to 20 applications per package. Because the higher concentrated alkaline products account for a small share of the units of all alkaline drain openers sold, 11 one would expect that the proportion of consumer applications of chemical drain openers that involve a SADO would be somewhat higher than the market share of SADOs, based on packages sold. If on average consumers get twice as many applications from a package of sulfuric acid drain opener as from a package of alkaline drain opener, in terms of the number of applications, SADOs could account for up to 10 percent of actual consumer applications. However, more data concerning the number of applications that consumers actually get from each type of product would be necessary before firmer estimates of the proportion of consumer applications of chemical drain openers that involve SADOs can be made.

The petitioner referred to an earlier CPSC estimate that consumers could be exposed to ALKDOs 40 to 280 times as frequently as to SADOs. 12 At the time that estimate was made, CPSC staff had no information regarding the market shares of the different types of drain openers. The high estimate was based on the assumption that virtually all of the ALKDOs sold were the dry or "crystal" products, which can have up to 20 applications per container. The

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⁸ Sales estimate is from Information Resources Incorporated and is for the 52 week period ended 10 September 2000. (Reported in: Tom Branna, "Clean and Convenient," <u>Household and Personal Products Industry</u>, December, 2000, p. 91.

⁹ Public Comment from Sulfuric Acid Drain Opener Manufacturers (28 August 2004).

¹⁰ Assuming drain pipes with two inch diameters.

According to Information Resources Incorporated, in the 52-week period ended 10 August 2003, dry alkaline drain openers accounted for about 6.5 percent of the sales of drain openers in grocery, drug, and discount/department stores. No estimate is available for the retail market share of the liquid ALKDOs with higher hydroxide concentrations, but Staff believes it to be low since they are not sold as widely as are the ALKDOs with the lower hydroxide concentrations.

 $^{^{12}}$ This estimate was contained in a CPSC staff memorandum from Roy Samarco to Virginia White, dated 24 February 1981.

market share of these products is actually closer to 6 or 7 percent. ¹³ It also assumed that the typical quart container of alkaline drain openers contained at least 4 applications, as opposed to our current estimate of 1 to 2 applications per quart for the most common ALKDOs. Finally, it assumed that SADOs represented just under 2 percent of the total number of chemical drain openers sold, which may have been a low estimate. ¹⁴ Therefore, based on the currently available information, the estimate that SADOs account for 3 to 10 percent of all consumer chemical drain opener applications (or ALKDOs are used about 10 to 33 times as frequently as SADOs) may be a more reasonable estimate.

Retail prices for liquid alkaline drain openers range from about \$1 to \$4 per use, depending on the brand, retailer, package size, and the number of applications the consumer actually obtains per quart. Retail prices for sulfuric acid drain openers appear to be a little lower per application, ranging from about \$0.80 to \$2.00 per application. Retail prices per application are the lowest for the dry or crystal alkaline products: \$0.2 to 0.65 per use.

Societal Cost of Drain Opener Injuries

The CPSC Injury Cost Model (ICM) estimates the societal cost of injuries based upon the age, diagnosis, and gender of the victim, and whether or not the victim was hospitalized as recorded in the cases from the National Electronic Injury Surveillance System (NEISS). The ICM uses the weights assigned to the NEISS cases to estimate the number of injuries that were treated in emergency departments, but it also imputes from these cases estimates of the number of medically-attended injuries treated in other settings, such as doctor's offices, ambulatory clinics, and those admitted directly to a hospital, bypassing the emergency department. The estimated societal cost of injuries includes the costs of medical treatment, work loss, pain and suffering, and liability insurance and litigation costs. ¹⁵ Based on the ICM estimates of drain opener injuries (NEISS product code 929) for the years 1995 through 2003, medically-attended injuries involving all chemical drain openers (including both alkaline and acids) result in about \$93 million in societal costs annually.

SADOs were involved in about 10 percent of the NEISS cases (from 1995 through 2003) where the type of drain opener involved could be determined. However, it should be noted that the type of drain opener could not be determined in more than half of the NEISS cases. ¹⁶ Of the

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¹³ Based on sales at grocery, drug, and department stores for the 52-week period ended 10 August 2003 as reported by Information Resources Incorporated, Chicago, Illinois.

¹⁴ Memorandum from Eleanor Helper and John Lindholm (Battelle Columbus Laboratories) to Roy Samarco (Consumer Product Safety Commission), "Comments of the Ad Hoc Association of Chemical Producers (ACP) Regarding Consumer Use of Sulfuric Acid Drain Cleaners, Dated June 5, 1980, (18 July 1980).

¹⁵ For a more thorough discussion of the ICM see Ted R. Miller, et al., The Consumer Product Safety Commission's Revised Injury Cost Model, Final Report to the U.S. Consumer Product Safety Commission, Public Services Research Institute, Calverton, Maryland, December 2000. It is available from the CPSC website (in 2 files) at http://www.cpsc.gov/LIBRARY/FOIA/FOIA02/os/Costmodept1.pdf and http://www.cpsc.gov/LIBRARY/FOIA/FOIA02/os/Costmodept2.pdf.

Robin L. Ingle, CPSC Memorandum to Kristina M. Hatlelid, "Petition Requesting Ban of Sulfuric Acid Drain Openers for Consumer Use, Petition HP 04-02, (2005).

drain opener exposures (from 1995 through 2003) reported through the Toxic Exposure Surveillance System (TESS) for all ages, 18 percent involved acid drain openers. However, this estimate includes exposures involving hydrochloric acid drain openers. ¹⁷

If injuries involving SADOs are more severe than the average injury involving drain openers, the average societal cost of injuries involving sulfuric acid drain openers would be higher than the average associated with all drain opener injuries. For example, if a higher proportion of SADO injuries require hospitalization, the average societal costs would be higher. There is some evidence suggesting that injuries involving SADOs may be on average more severe than injuries involving all alkaline drain openers. For example, according to the TESS data, 34 percent of all SADO exposures reported to a poison control center resulted in a moderate or worse outcome while 26 percent of the exposures to alkaline drain openers resulted in a moderate or worse outcome. 18 However, alkaline drain openers include products with sodium or potassium hydroxide concentrations ranging from less than 2 percent to more than 40 percent for liquids and from 60 percent to 100 percent for the granular. It is not possible, with the available data, to compare the outcomes of injuries associated with SADOs to the outcomes of injuries associated with the more concentrated alkaline drain openers (e.g., 10 percent hydroxide or greater) due to the fact that injuries associated with the more concentrated alkaline products are included with those associated with the less concentrated products. The less concentrated alkaline products would be expected to pose a lower risk of serious injury than the more concentrated products. As noted earlier, the more concentrated alkaline drain openers may be the closest substitute for SADOs.

Potential Impacts of Actions Requested by the Petitioner

The petitioner requested that the Commission ban SADOs for general consumer use. Although a ban was the petitioner's preferred action, the petitioner suggested that requiring SADOs be sold in single use and "one-shot" containers or limiting the sulfuric acid concentration to no greater than 84 percent could mitigate some of the risk. This section discusses some of the economic implications of each of the petitioner's proposals. However, a formal cost-benefit analysis is beyond the scope of this report.

Ban of Sulfuric Acid Drain Openers for Consumer Use

Effect on Societal Cost of Injuries: The petitioner assumes that if SADOs were banned, all of the injuries and societal costs now associated with SADOs would be eliminated. In fact, if SADOs were not available, the consumers who now use them would likely substitute other chemical drain openers, such as ALKDOs or drain openers containing other acids. In many cases consumers may substitute the ALKDOs with higher hydroxide concentrations, which like

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¹⁷ Robin L. Ingle, CPSC Memorandum to Kristina M. Hatlelid, "Petition Requesting Ban of Sulfuric Acid Drain Openers for Consumer Use, Petition HP 04-02, (2005).

¹⁸ Robin L. Ingle, CPSC Memorandum to Kristina M. Hatlelid, "Petition Requesting Ban of Sulfuric Acid Drain Openers for Consumer Use, Petition HP 04-02, (2005). This data includes some incidents that were intentional.

SADOs, can produce severe injuries. ¹⁹ The reduction in societal costs that could be expected from a ban on SADOs would be the difference in societal costs between injuries associated with SADOs and the expected societal costs of injuries associated with the substitutes for SADOs.

Other Effects on Consumers: SADOs are reportedly more effective at breaking up clogs made of cellulosic materials, such as paper and cloth, than are ALKDOs. If SADOs were no longer available, consumers who have clogs composed of cellulosic material, and who would have ordinarily purchased a SADO, would have to rely on other methods for removing the clog. Unless the consumer is able to use the various mechanical devices, the consumer will probably have to call a professional plumber. Therefore, for these types of clogs a ban would increase the cost of unclogging the drains by a factor of greater than 100 (from about \$1 with a SADO to over \$100 with a professional plumber). However, clogs composed primarily of cellulosic materials are probably a small fraction of all clogs. ALKDOs are reportedly as effective as SADOs on clogs composed of grease, soap scum, and hair, which account for most household clogs.

Effect on Suppliers: SADO manufacturers would be adversely affected by a ban. There are probably fewer than a dozen manufacturers of SADOs for the consumer market. Most of the manufacturers have fewer than 500 employees and so would meet the Small Business Administration criteria for being considered a small business. ²⁰ In some cases SADOs account for a large proportion of their sales. Other SADO manufacturers have a more diverse product line. However, a ban on SADOs would likely increase the demand for other drain opening products, including other chemical drain openers, mechanical drain openers, and professional drain cleaning services.

Limiting SADOs for Consumer Use to "One-Shot" Containers

According to package directions, a typical application of a sulfuric acid drain opener requires 4 to 8 ounces, or one cup or less. There are some pint-sized packages of SADOs available, but technically these could contain enough product for 2 to 4 applications. Manufacturers could incur some costs in retooling their facilities to accommodate the smaller containers and the cost per unit of the SADOs would increase. However, it should be noted that CPSC staff have not determined whether or not a smaller package size would actually reduce the number or severity of injuries associated with SADOs.

Limiting the Sulfuric Acid Concentration to 84 percent or Less

Two SADOs are currently on the market that have sulfuric acid concentrations of about 84 percent. These SADOs reportedly produce less heat when mixed with the water in a clogged drain. The lower temperature (about 180°F vs. 220°F) reduces the risk that the acid will cause the water in the drain to boil or erupt out of the drain. One manufacturer claims that their product

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¹⁹ Patricia M. Brundage, CPSC Memorandum to Kristina Hatlelid, "Health Hazards Associated with Sulfuric Acid Drain Openers," (2005).

²⁰ Based on the Small Business Administration Criteria for NAICS code 325612 (Polish and other sanitation goods manufacturing), available at https://ewebl.sba.gov/naics/.

will "bead up" on dry skin which will allow the consumer additional time to wipe or rinse the product off before serious injury results. However, CPSC staff have not determined the extent of the risk reduction, if any. The cost of these sulfuric acid drain openers is somewhat higher than the cost of other SADOs, due to the fact that they contain additional ingredients that the manufacturers believe impart desirable properties to their products. These include additional corrosion inhibiters, coloring agents, buffering agents, and so on.

Summary

Sulfuric acid drain openers probably account for 3 to 5 percent of the packages of chemical drain openers sold to consumers, but because a typical application requires fewer ounces than required by the more common liquid alkaline drain openers, SADOs may account for up to 10 percent of the chemical drain opener treatments used by consumers. Likely substitutes for SADOs are hydrochloric acid drain openers and alkaline drain openers, especially the ALKDOs with higher hydroxide concentrations. However, SADOs are reportedly more effective on clogs composed of cellulosic material than are ALKDOs.

Because consumers would probably substitute other chemical drain openers for SADOs if SADOs were banned, the societal costs now associated with SADOs would not be eliminated. The extent to which these costs could be reduced has not been determined. Other options include requiring SADOs to be sold in single-use containers and to limit the sulfuric acid concentration to no more than 84 percent. The extent to which either of these options would reduce the societal costs is not known. Each could increase the manufacturing cost of the product. There are some SADOs on the market currently that are packaged in one pint containers and others that have sulfuric acid concentrations of 84 percent or less.

TAB F



United States CONSUMER PRODUCT SAFETY COMMISSION Washington, D.C. 20207

MEMORANDUM

DATE : July 12, 2004

TO : HS

Through: Todd A. Stevenson, Secretary

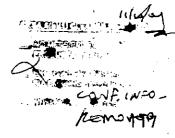
FROM : Martha Kosh

SUBJECT: Petition HP 04-2, Requesting Ban on Sulfuric

Acid Drain Openers for Consumer Use

ATTACHED ARE COMMENTS ON THE ____CH 04-5

COMMENT	DATE	SIGNED BY	<u>AFFILIATION</u>
CH04-5-1	6/06/04	Stuart Bush President & CEO	Roebic Laboratories, Inc. 25 Connair Road Orange, CT 06477
	i	Keith Onsdorff Atty Special Counsel For Federal Regu	iatorv
		Issues	
CH04-5-2	7/2/04	Joon S. Moon Chairman	The Rooto Corporation 3505 West Grand River Howell, MI 48843
CH04-5-3	7/6/04		Amazing Products, Inc. P.O. Box 14226 Louisville, KY 40214
CH04-5-4	8/28/04 (LATE)	Industry Members	Sulfuric Acid Industry Manufacturers
			(OUD PURTIONS ROMOVED



TAB G

Date: 12 September 2005

TO

Mary Ann Danello, Ph.D., Associate Executive Director, Directorate for Health

Sciences

THROUGH:

Memorandum

Lori E. Saltzman, M.S., Director, Division of Health Sciences, Directorate for W

Health Sciences

FROM

Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health

Sciences

SUBJECT:

Response to Public Comments on Petition HP 04-2

Introduction

On 26 February 2004, the U.S. Consumer Product Safety Commission (CPSC) received a request from Michael Fox, Ph.D. that the Commission ban sulfuric acid drain cleaners (SADOs) for use by consumers, or in the alternative, that the Commission require SADOs for consumers be packaged in one-shot containers and be limited to a maximum sulfuric acid concentration of 84 percent. This requests was docketed under the Federal Hazardous Substances Act (FHSA) as Petition No. HP 04-2 on 1 April 2004.

The U.S. Consumer Product Safety Commission (CPSC) received public comments and information from three organizations in response to the notice published in the <u>Federal Register</u> on 5 May 2004 (69 FR 25069). This memo provides a summary of those submissions and the staff's responses to them. The index of the public comments on the petition is in Tab F. Comments were provided by two individual companies [Roebic Laboratories, Inc. (CH04-5-1) and The Rooto Corporation (CH04-5-2)] and one group of companies (CH04-5-3; CH04-5-4) that produce sulfuric acid drain opener products. These commenters opposed the request to ban sulfuric acid drain openers for consumer use and the call for additional restrictions on these products.

The Commission also received additional comments from the petitioner, Michael Fox, and from the previous petitioner, Roger L. Wabeke (Petition HP 95-3), reiterating the points they had made in their previous submissions.

Discussion

Comment CH04-5-1:

Roebic Laboratories, Inc. opposes the requested ban because the company believes that they have already taken steps to address the safety of their product. They stated that their sulfuric acid drain opener product is formulated to be less likely to cause thermal burns to the skin. They also stated that the black color of the product and a formulation that "beads" on the skin make it noticeable when a spill has occurred and make it easy to clean it off the skin using a

dry cloth. They also stated that they use an "anti-glug" spout to limit the spill, and they use over-packaging to protect against accidental spills when the product is transported.

CPSC Staff Response:

This company argues that they have formulated their product so as to limit spills, to be less likely to cause thermal burns to the skin, and to be easy to clean off the skin, but they have not provided any data that indicates the effectiveness of any of these characteristics. Although it's conceivable that these steps do provide a benefit, the staff has not tested the ability of these features to reduce the risk or severity of injury to consumers.

Comment CH04-5-2:

The Rooto Corporation opposes the ban because they believe that the injury data and economic factors do not support that action. They stated that they have been producers of sulfuric acid drain openers for more than 30 years and have sold more than 100 million applications. They claim that they have received fewer than 50 complaints, and that most of them were because of misuse or abuse.

Although the comments include little actual data, the firm claims that banning these products would greatly increase the cost of cleaning blocked drains and could cause more accidents. They believe that banning sulfuric acid products would benefit only plumbers, who would be using the same products currently available to consumers. Finally, they disagree that decreasing the acid concentration in the product would be beneficial.

CPSC Staff Response:

The staff agrees that the alternatives to sulfuric acid drain openers could be more costly to consumers. SADOs are reportedly more effective than alkaline-based products at breaking up clogs made of cellulosic materials, such as paper and cloth. If SADOs were no longer available, consumers who have clogs composed of cellulosic material would have to rely on other methods for removing the clog, such as hiring a professional plumber. However, the staff believes that only a fraction of clogs would only respond to a sulfuric acid drain opener or a method other than an alkaline drain opener.

Comment CH04-5-3, CH04-5-4:

These comments were submitted by a group of nine sulfuric acid drain opener producers. The firms represented in these comments were formerly members of a consortium of sulfuric acid manufacturers known as the Association of Chemical Producers, Inc. (ACP). The ACP was discontinued in 2002 purportedly due to costs associated with legal representation of the group (Personal communication, J. Whitlock, Amazing Products, 2005). These commenters oppose the ban and address some specific claims made by the petitioner.

The commenters disagreed with the petitioner's claims that the ACP lacked necessary expertise and was ineffective. These companies believe that their membership brought to the

¹ Robert Franklin, CPSC Memorandum to Kristina Hatlelid, "Petition to Ban Sulfuric Acid Drain Openers: Market Information and Economic Considerations," (2005).

ACP many years of knowledge and experience and that the member companies did conform to the established minimum standards.

The commenters dispute the petitioner's claims that most SADO sales are to professionals, which would lead to the conclusion that a small proportion of all SADO sales are responsible for injuries to consumers. The commenters assert that 93-95% of SADO sales are to consumers, and that sales and the economic benefits of SADOS are large compared to a small number of injuries. They believe that SADOs are useful for certain kinds of drain blockages and that alternatives to SADOS would be costly (e.g., require services of a plumber). They disagree that the product labeling and warnings are ineffective, and they believe that criminal or intentional misuse of sulfuric acid, as highlighted by the petitioner, is irrelevant.

The commenters believe that the petitioner's list of CPSC product recalls and other actions is irrelevant and misleading since the list included products that were defective, primarily intended for children or entertainment purposes, involved flammability, or involved products that had readily available alternative formulations. These firms further commented on the example of an oven cleaner product recalled because of an improperly attached valve assembly. The petitioner mentioned that the oven cleaner is chemically similar to alkaline drain openers. These commenters emphasized that this example demonstrates "that caustic compounds (similar to the subject of this discussion) are acceptable for household use even under pressure in aerosol form, unlike the sulfuric acid drain openers, which are in much safer and superior packaging."

The commenters disagree with the petitioner's claims that the quality of the incident data is affected by the "Kleenex syndrome," in which sulfuric acid products are likely to be misidentified as the alkaline product "Liquid Plumber" because Liquid Plumber has become the generic term for drain openers. While the petitioner claimed that this results in underestimating the number and severity of SADO injuries compared to alkaline product-related injuries, the industry commenters believe that the data "must be accepted under the belief that it is predominantly correct."

CPSC Staff Response:

Although these commenters refuted many of the claims made in the petition, they provided little data to support their own claims. The staff agrees that sulfuric acid products may work better than other types of chemical drain openers for certain clogs, but we believe that these clogs are only a small fraction of all clogs². In general, while their positions are noteworthy, the lack of substantive data in this comment makes it difficult for the staff to apply the information to its analysis.

Conclusions

The responses to the <u>Federal Register</u> of 5 May 2004, all from producers of sulfuric acid drain opener products, oppose a ban of sulfuric acid drain opener products and oppose packaging and formulation restrictions. However, none of these comments provide substantive data or concrete information concerning the petition. Therefore, little of the information can be used directly in the staff's analysis.

² Robert Franklin, CPSC Memorandum to Kristina Hatlelid, "Petition to Ban Sulfuric Acid Drain Openers: Market Information and Economic Considerations," (2005).

The additional comments from the petitioner and from the previous petitioner reiterated their views that sulfuric acid drain opener products should be banned or otherwise regulated. Their comments included the points they had made in their previous submissions, but offered no new substantive information.